Regulations and Curriculum for Bachelor of Pharmacy (B.Pharm)

(Semester Scheme) 2016

[Framed as per the provisions of section 6, 7 & 8 of the Bachelor of Pharmacy (B.Pharm) course regulations 2014 of Pharmacy Council of India]

(Deemed to be University under Section 3 of UGC Act, 1956)
(Placed under Category 'A' by MHRD, Govt. of India, Accredited with 'A' Grade by NAAC)
University Enclave, Deralakatte, Mangaluru – 575 018
Tel: +91-824-2204300/01/02/03, Fax: 91-824-2204305
Website: www.nitte.edu.in E-mail: info@nitte.edu.in

VISION

To build a humane society through excellence in education and healthcare

MISSION

To develop
Nitte (Deemed to be University)
As a centre of excellence imparting quality education,
generating competent, skilled manpower to face the scientific and social
challenges with a high degree of credibility, integrity,
ethical standards and social concern

PEO STATEMENTS

PEO1: High quality pharmacy education with knowledge, skill and attitude

PEO2: Innovation and research, critical thinking, scientific temperament

PEO3: Better interaction with other health care professionals

PEO4: Proficiency in formulation, analysis, testing and validation of drugs and pharmaceutical

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Curriculum

I Semester B.Pharm

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No. F.9-13/2007-U.3 (A)
Government of India
Ministry of Human Resource Development
(Department of Higher Education)
U.3 (A) Section

Shastri Bhavan, New Delhi
Dated: 4th Jun, 2008

NOTIFICATION

1. Whereas the Central Government is empowered under Section 3 of the University Grants Commission (UGC) Act, 1956 to declare, on the advice of the UGC, an institution of higher learning as a deemed-to-be-university;
2. And whereas, a proposal was received in February, 2007 from Nitte Education Trust, Mangaluru, Karnataka seeking grant of status of deemed-to-be university in the name of Nitte (Deemed to be University) under section 3 of the UGC Act, 1956;
3. And whereas, the University Grants Commission has examined the said proposal and vide its communication bearing No. F.26-10/2007(CPP-I/DU), dated the 10th March, 2008 has recommended conferment of status of deemed-to-be-university in the name and style of Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Mangaluru.
4. Now, therefore, in exercise of the powers conferred by section 3 of the UGC Act, 1956, the central Government, on the advice of the University Grants Commission (UGC), hereby declare that Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru, shall be deemed to be a University for the Purposes of the aforesaid Act.

Sd/
(Sunil Kumar)
Joint Secretary to the Government of India

(True Extract of the Notification)

University Grants Commission
Bahadurshah Zafar Marg
New Delhi – 110002

No. F.26-5/2008(CPP-1) Dated: 24th March, 2009

OFFICE MEMORANDUM

1. Whereas the Government of India, Ministry of Human Resource Development, Department of Higher Education vide Notification No. F.9-13/2007-U3(A) dated 4th June, 2008 declared Nitte (Deemed to be University), Mangaluru, Karnataka comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru as Deemed to be University under Section 3 of UGC Act, 1956.
2. And whereas now, the University Grants Commission, on the recommendation of an Expert Committee constituted by the Chairman, UGC has agreed for bringing (i) K. S. Hegde Medical Academy, Deralakatte, Mangaluru (ii) Nitte Usha Institute of Nursing Sciences, Deralakatte, Mangaluru (iii) Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Deralakatte, Mangaluru, (iv) Nitte Institute of Physiotherapy, Deralakatte, Mangaluru under the ambit of Nitte (Deemed to be University), Deralakatte, Mangaluru.

Sd/
(K. P. Singh)
Joint Secretary, University Grants Commission

(True Extract of the Office Memorandum

Nitte University

(Deemed University under Section 3 of UGC Act, 1956)
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Ref. No. NU/REG/AC/2015-16/597 Date: 01-02-2016

NOTIFICATION

Subject: Regulations and Curriculum for Bachelor of Pharmacy (B.Pharm)

Reference: Minutes of the Academic Council meeting held on 28th Jan. 2016

In exercise of the Powers conferred under Rule R-08 (g) of the Memorandum of Association, the Academic Council has been pleased to approve the Regulations and Course Curriculum for the B.Pharm Course (Semester Scheme) in the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences.

The Regulations and course curriculum shall come into force from the academic year 2016-17.

By Order,

Registrar

NITTE (Deemed to be University)
(Deemed to be University under section 3 of UGC Act 1956)
Placed under Category 'A' by MHRD, Govt. of India
Accredited as 'A' Grade University by NAAC
Mangaluru, Karnataka, India

Regulations and Curriculum for Bachelor of Pharmacy (B. Pharm)

Preamble:

Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, imparting education and training in pharmaceutical sciences since 1983, started B. Pharm program in 1984. M.Pharm programs were introduced in 1991. From the year 2009-10 the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences became a constitute college of Nitte (Deemed to be University). The Pharm.D program was started in the year 2012-13. Consequent to introducing semester system for B.Pharm program as per PCI course regulations 2014, the new regulations are formulated as under:

1. Introduction

1.1 These regulations shall be called as revised regulations for the B.Pharm degree program of Nitte (Deemed to be University). The Regulations for B.Pharm program shall govern the policies and procedures including selection, admission, imparting of instructions, conduct of examinations, evaluation and certification of candidate's performance and all amendments there to, leading to the award of B. Pharm degree. The regulations are in conformance with "The Revised Regulations for B.Pharm. degree program of Pharmacy Council of India" and All India Council for Technical Education (AICTE) regulations of Bachelor of Pharmacy (B.Pharm) degree program.

1.2 This set of regulations shall be binding on all the candidates undergoing the said degree programme. The regulations shall come into effect from the academic year 2016-17.

1.3 These regulations may be modified from time to time as mandated by the statutes of the University, the AICTE and the PCI.

1.4 This set of regulations may evolve and get refined or updated or amended or modified or changed through appropriate approvals from the Academic Council or the Board of Management from time to time and shall be binding on all parties

concerned including the candidates, faculty, staff, departments and institute authorities.

1.5 All disputes arising from this set of regulations shall be addressed to the Board of Management. The decision of the Board of Management is final and binding on all parties concerned. Further, any legal disputes arising out of this set of regulations shall be limited to the jurisdiction of Courts of Mangaluru only.

2. Definitions:

Unless the context otherwise requires

- *Academic Year* means two consecutive (one odd + one even) semesters
- *BOM* means Board of Management of Nitte (Deemed to be University)
- *BOS* means Board of Studies in Pharmaceutical Sciences
- *College/Institution* means Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences
- He includes both genders He and She; similarly his and / or him, himself includes her, as well in all cases
- *Head of the Institution means the Principal of the College (Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences)*
- *Regulations means this set of academic regulations*
- *Regulatory Authority – Authority appointed / constituted by the central / state government/s to regulate Pharmaceutical Sciences Education*
- *University means Nitte (Deemed to be University)*
- *Program means a set of courses which the student has to complete for the award of B.Pharm. degree*
- *Course means a subject or a paper. A course may comprise either theory or practical listed under the program*
- *Audit Course means course/s aimed at supplementing a candidate's knowledge and /or skills. These courses will carry credit points, but there will not be end semester examination conducted by the University.*
- *Credit means a unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture) or two hours of tutorials or two hours of laboratory /practical/ project work per week*
- *Semester Grade Point Average (SGPA) means a measure of performance of work done in a semester. It is ratio of total credit points secured by a student in various courses registered in a semester and the total course credits taken during that semester. It shall be expressed up to two decimal places*

- *Cumulative Grade Point Average (CGPA) means a measure of overall cumulative performance of a student over all semesters. The CGPA is the ratio of total credit points secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed up to two decimal places.*
- *Letter Grade is an index of the performance of a candidate in a said course. Grades are denoted by letters O, A, B, C, D, E, F and AB*
- *Grade Point means a numerical weight allotted to each letter grade on a 10-point scale.*
- *CIE means Continuous Internal Evaluation*
- *SEE means Semester End Examination*

3. Duration of the Program:

The program of study for B. Pharm is four academic years (eight semesters) and three academic years (six semesters) for lateral entry students. Semester system is followed for B.Pharm program.

4. Medium of Instruction and Examinations:

The medium of Instruction and Examination is English.

5. Maximum Period for completion of the program:

The maximum period for completion of the B Pharm program is eight years and six years for lateral entry students.

6. Minimum qualification for Admissions:

No candidate shall be admitted to the curriculum of the first year of B.Pharm program until:

6.1 He has completed the age of 17 years on or before the 31st December of the year of admission and

6.2 He has passed qualifying examination as under:

The two year PUC examination of Karnataka PU Board or an equivalent examination of any other approved by the Board / Association of Indian Universities (AIU) with English as one of the subjects not less than 45% marks in any combination comprising

- Physics, Chemistry, Mathematics
- Physics, Chemistry, Biology

- Physics, Chemistry, Mathematics, Biology

In respect of candidates who have taken Physics, Chemistry, Mathematics, Biology combination the aggregate of Physics, Chemistry, Mathematics OR Physics, Chemistry, Biology whichever is higher will be considered for the purpose of admission. He must have studied English as one of the languages as a core subject.

Note:

1. Candidates who have passed D.Pharm program in an institution approved by Pharmacy Council of India under section 12 of the Pharmacy Act shall also be eligible to this program and shall be admitted to III Semester B.Pharm program.
2. For SC/ST or category I Candidates, the minimum percentage of marks shall be 40% in P.U.C. or its equivalent examination (P.C.B, or P.C.M. or P.C.M.B) or D. Pharm.
   Foreign students seeking admission should obtain the approval from Nitte (Deemed to be University) after establishing the equivalence of the qualification.

7. Re-admission after break of study:

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

8. Withdrawal -Temporary and Permanent:

8.1 **Temporary:**

8.1.1. A candidate who has been admitted to the program may be permitted to withdraw temporarily for a period of six months or more up to one year on the grounds of prolonged illness, grave calamity in the family etc., provided:

a. He applies stating the reason of withdrawal with supporting documents and endorsement by parent/guardian.
b. The Institute is satisfied that without counting the period of withdrawal candidate is likely to complete his requirement of the degree within maximum time specified.
c. There are no outstanding dues or demands with the department,

library, hostel, college etc.

8.1.2. The tuition fee for the subsequent year may be collected in advance based on the severity of the case before giving approval for any such temporary withdrawal

8.1.3. Scholarship holders are bound by the appropriate rules applicable

8.1.4. The decision of the College/University regarding withdrawal of a candidate is final and binding.

8.2. **Permanent withdrawal:**

8.2.1. A candidate who withdraws admission before closing date of admission for the academic session is eligible for the refund of the deposit only. The fees once paid will not be refunded on any account.

8.2.2. Once the admission for the year is closed, and if a candidate wants to leave the institution, he will be permitted to do so and take the Transfer Certificate from the college, if required only after remitting all the tuition fees for the remaining years.

8.2.3. Those candidates who have received any scholarship/stipend/other forms of assistance from the college shall repay all such amounts in addition to those mentioned in the clause above.

8.2.4. The decision of the college/university regarding withdrawal of a candidate is final and binding.

9. Conduct and discipline:

9.1. Candidates shall conduct themselves within and outside the premises of the Institute in a manner befitting the student of professional Institution.

9.2. **As per the order of Honorable Supreme Court of India, ragging in any form is considered as a criminal offence and is banned. Any form of ragging will be severely dealt with.**

9.3. The following act of omission and/or commission shall constitute gross violation of the code of conduct and are liable to invoke disciplinary measures:

9.3.1. Ragging as defined and described by the Supreme Court/Government

9.3.2. Lack of courtesy and decorum; indecent behaviour anywhere within or outside the campus.

9.3.3. Willful damage or stealthy removal of any property/belongings of the College/Hostel or of fellow candidates/citizens.

9.3.4. Possession, consumption or distribution of alcoholic drinks or any kind of hallucinogenic drugs.

9.3.5. Mutilation or unauthorized possession of library books.

9.3.6. Noisy or unseemly behavior, disturbing studies of fellow candidates.

9.3.7. Hacking in computer systems (such as entering into other person's domain without prior permission, manipulation and/or damage to the computer hardware and software or any other cyber crime etc.)

9.3.8. Plagiarism of any nature.

9.3.9. Any other act of gross indiscipline as decided by the Board of management from time to time.

9.4. Commensurate with the gravity of offense, the punishment may be: reprimand, fine, expulsion from the hostel, debarment from an examination, disallowing the use of certain facilities of the Institute, rustication for a specific period or even outright expulsion from the Institute, or even handing over the case to appropriate law enforcement authorities or the judiciary, as required by the circumstances.

9.5. For any offence committed in (i) a hostel (ii) a department or in a classroom and (iii) elsewhere, the Chief Warden, the Head of the Department and the Head of the Institution, respectively, shall have the authority to reprimand or impose fine.

9.6. All cases involving punishment other than reprimand shall be reported to the Vice- chancellor.

9.7. Cases of adoption of unfair means and/or any malpractice in an examination shall be reported to the Controller of Examinations for taking appropriate action.

10. Working days in each semester:

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

11. Attendance and progress:

11.1 A candidate pursuing B.Pharm program shall study in the concerned department of the institution for the entire period as a full time candidate. No candidate is permitted to work in any outside laboratory / institution / industry / pharmacy, etc., during the period of study. No candidate shall join any other course of study or appear for any other degree examination conducted by this university or any other university in India or abroad during the period of registration.

11.2 Each semester shall be taken as a unit for the purpose of calculating attendance.

11.3 A candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately and who has fulfilled all other requirements of

the program shall be permitted to appear for the University examination.

11.4 A Candidate who doesn't fulfill the requirements of attendance shall not eligible to appear for the examination and repeat the semester when it is offered next.

12. Program/Course credit structure:

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

12.1 **Credit assignment:**

12.1.1. **Theory and Laboratory courses:**

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

12.2 **Minimum credit requirements:**

The minimum credit points required for award of a B. Pharm. degree is 210. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Project over the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D.Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively,

a total of 7 credit points to match 59 credit points, the maximum of I and II semesters.

13. Course of study:

The course of study for B.Pharm shall include Semester wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table – I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH11T	Human Anatomy and Physiology I - Theory	3	1	4
16BPH12T	Pharmaceutical Analysis – Theory	3	1	4
16BPH13T	Pharmaceutics I- Theory	3	1	4
16BPH14T	Pharmaceutical Inorganic Chemistry - Theory	3	1	4
16BPH15T	Communication skills - Theory *	2	-	2
16BPH16T 16BPH17T	Remedial Biology/ Remedial Mathematics - Theory*	2	-	2
16BPH11P	Human Anatomy and Physiology I - Practical	4	-	2
16BPH12P	Pharmaceutical Analysis – Practical	4	-	2
16BPH13P	Pharmaceutics I – Practical	4	-	2
16BPH14P	Pharmaceutical Inorganic Chemistry - Practical	4	-	2
16BPH15P	Communication skills - Practical *	2	-	1
16BPH16P	Remedial Biology - Practical*	2	-	1
	Total	32/34$/36#	4	27/29$/30#

#Applicable for the students appearing for Remedial Biology course.

$Applicable for the students for Remedial Mathematics course.

* Non University Examination (NUE)

Table - II: Course of study for semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH21T	Human Anatomy and Physiology II - Theory	3	1	4
16BPH22T	Pharmaceutical Organic Chemistry I - Theory	3	1	4
16BPH23T	Biochemistry – Theory	3	1	4
16BPH24T	Pathophysiology – Theory	3	1	4
16BPH25T	Computer Applications in Pharmacy - Theory *	2	-	2
16BPH26T	Environmental Sciences – Theory*	2	-	2
16BPH21P	Human Anatomy and Physiology II – Practical	4	-	2
16BPH22P	Pharmaceutical Organic Chemistry I – Practical	4	-	2
16BPH23P	Biochemistry – Practical	4	-	2
16BPH25P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	30	4	27

* Non University Examination (NUE)

Table - III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH31T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
16BPH32T	Physical Pharmaceutics I- Theory	3	1	4
16BPH33T	Pharmaceutical Microbiology – Theory	3	1	4
16BPH34T	Pharmaceutical Engineering – Theory	3	1	4
16BPH31P	Pharmaceutical Organic Chemistry II - Practical	4	-	2
16BPH32P	Physical Pharmaceutics I – Practical	4	-	2

16BPH33P	Pharmaceutical Microbiology – Practical	4	-	2
16BPH34P	Pharmaceutical Engineering – Practical	4	-	2
	Total	28	4	24

Table - IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH41T	Pharmaceutical Organic Chemistry III – Theory	3	1	4
16BPH42T	Medicinal Chemistry I – Theory	3	1	4
16BPH43T	Physical Pharmaceutics II – Theory	3	1	4
16BPH44T	Pharmacology I – Theory	3	1	4
16BPH45T	Pharmacognosy & Phytochemistry I – Theory	3	1	4
16BPH42P	Medicinal Chemistry I – Practical	4	-	2
16BPH43P	Physical Pharmaceutics II – Practical	4	-	2
16BPH44P	Pharmacology I – Practical	4	-	2
16BPH45P	Pharmacognosy & Phytochemistry I – Practical	4	-	2
	Total	31	5	28

Table - V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH51T	Medicinal Chemistry II – Theory	3	1	4
16BPH52T	Industrial Pharmacy I– Theory	3	1	4
16BPH53T	Pharmacology II – Theory	3	1	4
16BPH54T	Pharmacognosy & Phytochemistry II – Theory	3	1	4
16BPH55T	Pharmaceutical Jurisprudence – Theory	3	1	4
16BPH52P	Industrial Pharmacy I – practical	4	-	2
16BPH53P	Pharmacology II – Practical	4	-	2

16BPH54P	Pharmacognosy & Phytochemistry II – Practical	4	-	2
	Total	27	5	26

Table - VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH61T	Medicinal Chemistry III – Theory	3	1	4
16BPH62T	Pharmacology III – Theory	3	1	4
16BPH63T	Herbal Drug Technology – Theory	3	1	4
16BPH64T	Biopharmaceutics and Pharmacokinetics- Theory	3	1	4
16BPH65T	Pharmaceutical Biotechnology – Theory	3	1	4
16BPH66T	Pharmaceutical Quality Assurance – Theory	3	1	4
16BPH61P	Medicinal Chemistry III – Practical	4	-	2
16BPH62P	Pharmacology III – Practical	4	-	2
16BPH63P	Herbal Drug Technology – Practical	4	-	2
	Total	30	6	30

Table - VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH71T	Instrumental Methods of Analysis – Theory	3	1	4
16BPH72T	Industrial Pharmacy II – Theory	3	1	4
16BPH73T	Pharmacy Practice – Theory	3	1	4
16BPH74T	Novel Drug Delivery System – Theory	3	1	4
16BPH71P	Instrumental Methods of Analysis – Practical	4	-	2
16BPH76	Practice School*	12	-	6
	Total	28	4	24

***** Non University Examination (NUE)

Table - VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
16BPH81T	Biostatistics and Research Methodology	3	1	4
16BPH82T	Social and Preventive Pharmacy	3	1	4
16BPH83ET	Pharma Marketing Management	3+3=6	1+1=2	4+4=8
16BPH84 ET	Pharmaceutical Regulatory Science			
16BPH85 ET	Pharmacovigilance			
16BPH86 ET	Quality Control and Standardizations of Herbals			
16BPH87 ET	Computer Aided Drug Design			
16BPH88 ET	Cell and Molecular Biology			
16BPH89 ET	Cosmetic Science			
16BPH90 ET	Pharmacological Screening Methods			
16BPH91 ET	Advanced Instrumentation Techniques			
16BPH92 ET	Dietary Supplements and Nutraceuticals			
16BPH93 ET	Pharmaceutical Product Development			
16BPH94	Project Work	12	-	6
	Total	24	4	22

Table – IX: Semester wise credit distribution

Semester	Credit Points
I	27/29$^{\$}$/30$^{\#}$
II	27
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Total credit points for the program	208/210$^{\$}$/211$^{\#}$

$^{\#}$Applicable for the students appearing for Remedial Biology course

$^{\$}$Applicable for the students for Remedial Mathematics course

14. Program Committee:

1. The B.Pharm programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the programme (one from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i) Periodically reviewing the progress of the classes.
   ii) Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii) Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters
   iv) Communicating its recommendation to the Head of the institution on academic matters.
   v) The Programme Committee shall meet at least thrice in a semester preferably at the end of each Sessional exam (Internal Assessment) and before the end semester exam.

15. Project work:

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
Total	**75 Marks**

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
Total	**75 Marks**

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

16. Industrial training:

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

17. Practice School:

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

18. Evaluation / Examinations:

The scheme for **Continuous Internal Evaluation (CIE)** and **Semester End Examinations(SEE)** is given in Table – X

18.1 **Continuous Internal Evaluation (CIE) :**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below:

Table – XI: Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	10	5
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	5	

Table – XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	4	2.0
90 – 94	3	1.5
85 – 89	2	1.0
80 – 84	1	0.5
Less than 80	0	0.0

18.1.1 **Sessional Exams:**

Two sessional exams shall be conducted for theory and one sessional exam for practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams in theory shall be computed for internal assessment as per the requirements given in Tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

1. Multiple Choice Questions (MCQs) (Answer all questions) = 10 x 1 = 10
2. Long Answers (Answer 1 out of 2) = 10 x 1 = 10
3. Short Answers (Answer 2 out of 3) = 10 x 1 = 10

Total = 30 marks

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For subjects having Non University examination

1. Long Answers (Answer 1 out of 2) = 10 x 1 = 10
2. Short Answers (Answer 4 out of 6) = 4 x 5 = 20

Total = 30 marks

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Question paper pattern for practical Sessional examinations

I.	Synopsis	= 10
II.	Experiments	= 25
III.	Viva voce	= 5

Total = 40 marks

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18.2. **Semester End Examinations**

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – X: Schemes for Continuous Internal Evaluation and Semester End Examinations semester wise

Semester I

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH11	Human Anatomy and Physiology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH12	Pharmaceutical Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH13	Pharmaceutics I- Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH14	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH15	Communication skills - Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
16BPH16 16BPH17	Remedial Biology/ Remedial Mathematics - Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
16BPH11P	Human Anatomy and Physiology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH12P	Pharmaceutical Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH13P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH14P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH15P	Communication skills- Practical*	5	5	2 Hrs	10	15	2 Hrs	25
16BPH16P	Remedial Biology - Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		**70/75$/80#**	**115/ 125$/ 130#**	**23/24$/26#**	**185/ 200$/ 210#**	**490/ 525$/ 540#**	**31.5/33$/ 35 #**	**675/ 725$/ 750#**

#Applicable for the students appearing for Remedial Biology course

$Applicable for the students for Remedial Mathematics course

***** Non University Examination (NUE)

Semester II

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		
		Continuous Mode	Sessional Exams			Marks	Duration	Total Marks
			Marks	Duration	Total			
16BPH21	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH22	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH23	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH24	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH25	Computer Applications in Pharmacy - Theory *	10	15	1 Hr	25	50	2 Hrs	75
16BPH26	Environmental Sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
16BPH21P	Human Anatomy and Physiology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH22P	Pharmaceutical Organic Chemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH23P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH25P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

***** The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH31	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH32	Physical Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH33	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH34	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH31P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH32P	Physical Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH33P	Pharmaceutical Microbiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH34P	Pharmaceutical Engineering – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28**	**600**

Semester IV

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH41	Pharmaceutical Organic Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH42	Medicinal Chemistry I– Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH43	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH44	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH45	Pharmacognosy & Phytochemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH42P	Medicinal Chemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH43P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH44P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH45P	Pharmacognosy & Phytochemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

Semester V

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH51	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH52	Industrial Pharmacy I - Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH53	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH54	Pharmacognosy & Phytochemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH55	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH52P	Industrial Pharmacy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH53P	Pharmacology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH54P	Pharmacognosy & Phytochemistry II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hrs**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH61	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH62	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH63	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH64	Biopharmaceutics and Pharmacokinetics - Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH65	Pharmaceutical Biotechnology – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH66	Pharmaceutical Quality Assurance – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH61P	Medicinal Chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH62P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH63P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

Semester VII

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH71	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH72	Industrial Pharmacy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH73	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH74	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH71P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
16BPH75	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8 Hrs**	**140**	**460**	**21 Hrs**	**600**

***** Non University Examination (NUE)

Semester VIII

Course code	Name of the course	Continuous Internal Evaluation (CIE)				Semester End Exams (SEE)		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration	Total			
16BPH81	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
16BPH82	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100

Elective Subjects (A student has to opt any two of the following Electives)								
16BPH83ET	Pharma Marketing Management – Theory	10+10=20	15+15 =30	1+1=2 Hrs	25+25 =50	75+75 =150	3+3=6	100+100 =200
16BPH84ET	Pharmaceutical Regulatory Science – Theory							
16BPH85ET	Pharmacovigilance – Theory							
16BPH86ET	Quality Control and Standardizations of Herbals – Theory							
16BPH87ET	Computer Aided Drug Design – Theory							
16BPH88ET	Cell and Molecular Biology – Theory							
16BPH89ET	Cosmetic Science – Theory							
16BPH90ET	Pharmacological Screening Methods – Theory							
16BPH91ET	Advanced Instrumentation Techniques – Theory							
16BPH92ET	Dietary							

	Supplements and Nutraceuticals							
16BPH93ET	Pharmaceutical Product Development							
16BPH94P	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

19. Criteria for Pass:

A candidate must secure at least 40% of marks in SEE and CIE separately. Further, a candidate shall be declared as pass if he secures 50% of marks (including CIE) in each course in theory and practical examinations separately.

Theory and practical components are considered as individual courses (with different subject code) for the purpose of pass criteria.

A candidate who fails in any course, have to appear only in the course failed in the subsequent examinations. That is, the candidate who fails either in theory or practical course has to appear only in theory or practical as the case be.

20. **Rules for grace marks:**

The subject Grace of 1% of the maximum of the total marks in the examination subject to a maximum of 5 will be awarded to failed course(s), provided on award of grace marks the candidate passes in that subject/examination. Award of grace marks shall not be applicable for compartmental examinations.

Subject grace awarded to a subject as per above shall be deducted from a subject which has the highest secured marks and on deduction the candidate should not fail in that subject. Secondly, if any one subject is not having marks more than the grace marks to be awarded than the minimum for passing, then the grace marks shall be awarded by deducting from two or more subjects such that total marks before gracing and after gracing shall remain the same. If there is no scope for deducting marks from other passed subjects to award marks for the failed subjects, grace marks shall not be awarded.

There shall be no provision to award grace marks for improvement of class.

21. Revaluation / Re-totaling of answer papers:

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for re-totaling by paying prescribed fee.

22. Improvement of CIE:

A student shall have the opportunity to improve his/her performance only once in the Sessional exam component of the CIE. The re-conduct of the Sessional exam shall be completed before the commencement of next SEE theory examinations.

23. Supplementary Semester End Examinations (SEE):

Supplementary SEE shall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table – XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

A candidate permitted to appear for the supplementary examination can improve his internal assessment marks before he takes the supplementary examination by subjecting himself to internal assessment procedure as practiced in the college.

Question paper pattern for SEE:

Sl. No	Question Type	Questions to be Set	Questions to be answered	Marks per Question	Total Marks
For 75 marks paper					
1	Multiple Choice Questions (MCQs)	**20**	**20**	**1**	**20 (20)**
2	Long Answers	**3**	**2**	**10**	**20 (30)**
3	Short Answers	**9**	**7**	**5**	**35(45)**
Total Marks to be answered (Total Marks to be set)					**75(95)**

Question paper pattern for CIE:

Sl. No	Question Type	Questions to be Set	Questions to be answered	Marks per Question	Total Marks
For 50 marks paper					
1	Long Answers (Answer 2 out of 3)	**3**	**2**	**10**	**20 (30)**

2	Short Answers (Answer 6 out of 8)	**8**	**6**	**5**	**30 (40)**
Total Marks to be answered (Total Marks to be set)					**50 (70)**

Sl. No	**Question Type**	**Questions to be Set**	**Questions to be answered**	**Marks per Question**	**Total Marks**
For 35 marks paper					
1	Long Answers (Answer 2 out of 3)	**2**	**1**	**10**	**10 (20)**
2	Short Answers (Answer 6 out of 8)	**7**	**5**	**5**	**25 (35)**
Total Marks to be answered (Total Marks to be set)					**35 (55)**

Question paper pattern for end semester practical examinations

Sl. No	**Question Type**	**Marks**
For 35 marks paper		
1	Synopsis	**5**
2	Experiments	**25**
	Viva voce	**5**
Total Marks to be answered (Total Marks to be set)		**35**

24. Academic Progression:

The student is permitted to carry over the courses to the next semester with following conditions:

a. A candidate who fails in I semester is allowed to move to II semester. The candidates with back log courses shall take both I semester backlog papers as well as II semester courses. Candidate with a backlog of not more than 4 courses in I & II semester put together is allowed to go to the III semester.

b. Candidates who have failed in not more than 4 courses of II semester and III semester (put together) and not having backlog of I semester papers are only permitted to go to IV semester.

c. Candidates who have failed in not more than 4 courses of III semester and IV semester (put together) and not having backlog of I and II semester papers are

only permitted to go to V semester.

d. Candidates who have failed in not more than 4 courses of IV semester and V semester (put together) and not having backlog of I, II and III semester papers are only permitted to go to VI semester.
e. Candidates who have failed in not more than 4 courses of V semester and VI semester (put together) and not having backlog of I, II, III and IV semester papers are only permitted to go to VII semester.
f. Candidates who have failed in not more than 4 courses of VI semester and VII semester (put together) and not having backlog of I, II, III, IV and V semester papers are only permitted to go to VIII semester.
g. The candidate is permitted to appear for the VIII semester examination along with the backlog courses of VI and VII semesters and should pass all the courses, including the backlog courses to be declared as having completed the course, provided all the criteria for completion of course are fulfilled.

25. Grading of performances:

25.1 **Letter grades and grade points allocations:**

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – XIV.

Table – XIV: Letter grades and grade points equivalent to Percentage of marks and performances

Marks Range (%)	Grade Point	Letter Grade	Description	
90 & Above	10	O	Outstanding	First Class with Distinction
80-89.9	09	A	Excellent	
75-79.9	08	B	Very Good	
60-74.9	07	C	Good	First Class
50-59.9	06	D	Fair	Second Class
Less than 50	0	F	Fail	Fail
Absent	0	AB	Fail	Fail

A learner who remains absent for any semester end examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

26. Semester Grade Point Average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses for which examinations are conducted by the university. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_2+C_2+C_3+C_4+C_5}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has a F or AB grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4* \text{ZERO} + C_5G_5}{C_2+C_2+C_3+C_4+C_5}$$

27. Cumulative Grade Point Average (CGPA):

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_2+C_2+C_3+C_4+C_5 +C_6+C_7+C_8}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,…. and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,….

28. Declaration of class:

The candidate, who has passed all the courses prescribed, shall be declared to have passed the program. Class will be awarded only to those who pass the entire examination in the first attempt.

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	: CGPA of 7.50 and above
First Class	: CGPA of 6.00 to 7.49
Second Class	: CGPA of 5.00 to 5.99

Candidates who pass the examinations in more than one attempt shall be declared to have passed in 'Pass' class irrespective of the percentage of marks secured.

An attempt means the appearance of a candidate for one or more courses either in part or full in a particular examination.

A candidate who fails in main examination and passes one or more subjects or all subjects in the supplementary examination is not eligible for award of class or distinction. Passing in supplementary examination by such candidates shall be considered as attempt.

If a candidate submits application for appearing for the regular examination but does not appear for any of the courses/subjects in the regular University examination, he can appear for supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc. are fulfilled and his appearing in the supplementary examination shall be considered as the first attempt.

Candidates who pass the subjects in the supplementary examinations are not eligible for the award of Gold Medal or Merit Certificate.

Conversion of CGPA into percentage:

The CGPA is converted into percentage by multiplying by 10.

Percentage Equivalence of Grade Points

Grade Points	Class
Above 7.50	Distinction
6.00-7.49	First Class
5.00-5.99	Second Class

Percentage Marks = Grade Point x 10

29. Award of Ranks:

Ranks and Medals shall be awarded on the basis of final CGPA obtained. In case, Lateral Entry candidates are admitted, Ranks and medals shall be awarded on the basis of final CGPA obtained of the common years of study for both regular and Lateral Entry students.

Further only those candidates who have completed the course and fulfilled all the requirements in the minimum number of years prescribed and who have passed each semester in the first attempt are only eligible for the award of ranks.

30. Award of Degree:

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Goals of Education and Training in Pharmaceutical Sciences of Nitte (Deemed to be University), Mangaluru

Institutional objective

NGSM Institute of Pharmaceutical Sciences, a constituent college of Nitte (Deemed to be University), in its 32 years of existence has emerged as a premier institution in the country imparting Pharmacy education. The B.Pharm. course offered by the college is accredited by the National Board of Accreditation (NBA).

The vision of the college is train the students to be competent professionals and develop an environment conducive for research. To achieve our vision, the college shall

- Evolve institutional objectives, which would be in consonance with the national goals and health policies.
- Shift the role of Pharmacy teachers from merely imparting knowledge to that of facilitators and motivators of student learning.
- Establish an institution for faculty development, preparation of learning resource materials and for improving evaluation methods.
- Encourage and facilitate for Industry-Academia interaction and research in the area of Pharmaceutical sciences.

Course objectives

The graduate programme in Pharmacy (B.Pharm.) has been evolved with the following objectives

- To provide high quality pharmaceutical education at all levels, to produce efficient pharmacists with enterprising and creative skills.
- To organize continuing educational programmes
- To impart the concept of better patient health care
- Should be capable of functioning independently in both rural and urban environment.
- To develop effective interaction with fellow health care professionals in hospitals, community and industry of newer developments in Pharmacy.
- To be a part of all national and international sponsored health education programmes.
- To educate the students in the management of disease prevention measures, community hygiene and better health.
- To inculcate critical thinking, clarity of expression, independent thinking and scientific temperament.

- To encourage active learning methods like group discussions, seminars, peer interactions etc., which would enable students to develop discipline, personality, communicating skills, and other qualities, which are necessary.

Knowledge and Understanding:

a. Adequate knowledge and scientific information regarding basic principles of Pharmaceutical Chemistry, Pharmaceutics including Cosmetics, Pharmacology and Pharmacognosy including Herbal drugs.
b. Adequate knowledge of practical aspects of synthesis, formulation and analysis of various pharmaceutical and herbal medicinal agents.
c. Adequate knowledge of practical aspects of delivering a quality assured product as per Pharmacopoeia, WHO and ISO standards.
d. Adequate knowledge of practical aspects of Pharmacological screening, biological standardization and in-vivo drug interactions.
e. Adequate knowledge of clinical studies for patient counseling leading to physical and social well being of patients.
f. Adequate knowledge of practical aspects of product detailing and marketing of pharmaceutical products.

Skills:

a. Able to synthesize, purify, identify and analyze medicinal agents.
b. Able to formulate, store, dispense, analyze the prescriptions and / or manufacture the medicinal agents at commercial level.
c. Able to learn and apply the quality assurance principles including legal and ethical aspects involving drugs.
d. Able to extract, purify, identify and know the therapeutic value of herbal / crude / natural products.
e. Able to screen various medicinal agents using animal models for pharmacological activity.

Attitudes:

a. Willing to apply the current knowledge of pharmacy in best interest of patients and the community.
b. Maintain a high standard of professional ethics in discharging professional obligations.
c. Continuously upgrade professional information and be conversant with latest advances in Pharmacy field to serve the community better.
d. Willing to participate in continuing education programmes of PCI and AICTE to

upgrade knowledge and professional skills.

e. To help and to participate in the implementation of National Health Programmes.

Programme Outcomes

At the end of the program, graduates will be able to...

- Develop critical thinking, clarity of expression and scientific temperament.
- Acquire sound knowledge in the areas of synthesis and assay of medicinal agents including mode of action, drug interactions
- Acquire an in-depth knowledge of formulation, storage and analysis of various pharmaceutical dosage forms including herbal medicines required for both large scale commercial production and research.
- Acquire adequate knowledge about screening of drugs for several pharmacological activities and understand the mechanism of action of drugs.
- Understand the role of pharmacist in health care system and develop skill to interact with other professionals.
- Be capable of functioning independently in both rural and urban environment with adequate knowledge and skill in the area of health care.
- Able to educate the community about disease prevention measures, community hygiene and better health.

I SEMESTER

16BPH11: HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Outcome

At the end of the course students will be able to...

CO No.	Outcome statement
CO1	Explain the anatomy, physiology and functions of various Tissues and cell, organization of cellular system.
CO2	Understand the homeostatic mechanisms and altered physiology of skeletal system and joints
CO3	Understand the homeostatic mechanisms and altered physiology of peripheral nervous system
CO4	Understand the homeostatic mechanisms and altered physiology of nervous system
CO5	Understand the homeostatic mechanisms and altered physiology of endocrine system
CO6	Understand the homeostatic mechanisms and altered physiology of integumentary system sensory organs and its functions.

CO7	Apply the knowledge gained to understand the disease development and its progression.
CO8	Apply the basic knowledge gained by this course to understand the other disciplines of pharmacy subjects, understand drug actions

Course Content:

Unit I	**10 hours**
• **Introduction to human body** Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology. • **Cellular level of organization** Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine • **Tissue level of organization** Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.	
Unit II	**10 hours**
• **Integumentary system** Structure and functions of skin • **Skeletal system** Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction • **Joints** Structural and functional classification, types of joints movements and its articulation	
Unit III	**10 hours**
• **Body fluids and blood** • Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system. • **Lymphatic system:** Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system	

Unit IV	**08 hours**
• **Peripheral nervous system**: Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves. • **Special senses** Structure and functions of eye, ear, nose and tongue and their disorders.	
Unit V	**07 hours**
• **Cardiovascular system** Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.	

16BPH11P: HUMAN ANATOMY AND PHYSIOLOGY-I (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.`

7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

16BPH12: PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

Course Outcome

At the end of the course students will be able to...

CO1	Explain the various methods of expressing concentration and requirement of primary standards.
CO2	Describe the preparation and standardization of different reagents used in volumetric analysis.
CO3	Discuss validation of results achieved in analytical measurements.
CO4	Explain the principle of acid base, nonaqueous and precipitation titration with examples.
CO5	Describe the principle of complexometric and gravimetric estimation with examples.
CO6	Discuss the principle of various redox titration and diazotisation titration with examples.
CO7	Explain the principle of conductometry and potentiometry.
CO8	Describe the principle of polarography and different electrodes used in polarography.

Course Content:

UNIT I	10 Hours
(a) **Pharmaceutical analysis**- Definition and scope i) Different techniques of analysis ii) Methods of expressing concentration iii) Primary and secondary standards. iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate (b) **Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures (c) Pharmacopoeia, sources of impurities in medicinal agents, limit tests	
UNIT II	**10 Hours**
• **Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves • **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl	
UNIT III	**10 Hours**
• **Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride. • **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate. • **Gravimetry:** Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate. • Basic Principles, methods and application of diazotisation titration	
UNIT IV	**08 Hours**
Redox titrations (a) Concepts of oxidation and reduction (b) Types of redox titrations (Principles and applications) Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate	

UNIT V	07 Hours
• **Electrochemical methods of analysis** • **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications. • **Potentiometry -** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications. • **Polarography -** Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications	

16BPH12P: PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Preparation and standardization of

(1) Sodium hydroxide
(2) Sulphuric acid
(3) Sodium thiosulfate
(4) Potassium permanganate
(5) Ceric ammonium sulphate

II Assay of the following compounds along with Standardization of Titrant

(1) Ammonium chloride by acid base titration
(2) Ferrous sulphate by Cerimetry
(3) Copper sulphate by Iodometry
(4) Calcium gluconate by complexometry
(5) Hydrogen peroxide by Permanganometry
(6) Sodium benzoate by non-aqueous titration
(7) Sodium Chloride by precipitation titration

III Determination of Normality by electro-analytical methods

(1) Conductometric titration of strong acid against strong base
(2) Conductometric titration of strong acid and weak acid against strong base
(3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia

16BPH13: PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Outcome

At the end of the course students will be able to...

CO1	Explain history of profession of Pharmacy in India & Pharmacopeia and its development.
CO2	Learn parts and handling of prescription, posology & dose calculation of drug in children. Different types of dosage form
CO3	Elaborate different pharmaceutical calculation involved in formulation
CO4	Understand basic requirement and formulation of powder and liquid (monophasic& biphasic) dosages form
CO5	Explain type of Pharmaceutical incompatibility
CO6	Learn basic requirement, formulation and evaluation of suppositories and pessaries
CO7	Understand the mechanisms of drug penetration and also the factors influencing permeation through transdermal route
CO8	Explain the formulation and evaluation of semisolid preparation such as ointment, gel cream etc.

Course Content:

UNIT – I	10 Hours
• **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia. • **Dosage forms:** Introduction to dosage forms, classification and definitions • **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription. • **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.	
UNIT – II	**10 Hours**
• **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight. • **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions. • **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques	
UNIT – III	**08 Hours**
• **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions. • **Biphasic liquids:** • **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome. • **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.	

UNIT – IV	**08 Hours**
• **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories. • **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.	
UNIT – V	**07 Hours**
Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms	

16BPH13P: PHARMACEUTICS I (Practical)

4 Hours / week

1. Syrups a) Syrup IP'66
b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir
b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66
b) Iodine Throat Paint (Mandles Paint)

4. Solutions a) Strong solution of ammonium acetate
b) Cresol with soap solution
c) Lugol's solution

5. Suspensions a) Calamine lotion
b) Magnesium Hydroxide mixture
c) Aluminimum Hydroxide gel

5. Emulsions a) Turpentine Liniment
b) Liquid paraffin emulsion

6. Powders and Granules
a) ORS powder (WHO)
b) Effervescent granules
c) Dusting powder
d) Divded powders

7. Suppositories
a) Glycero gelatin suppository
b) Coca butter suppository
c) Zinc Oxide suppository

8. Semisolids
a) Sulphur ointment
b) Non staining iodine ointment with methyl salicylate
c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle
b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York

16BPH14: PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- Know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- Understand the medicinal and pharmaceutical importance of inorganic compounds

Course Outcome

At the end of the course students will be able to...

CO1	Explain the sources of impurities and methods to determine the impurities in inorganic pharmaceuticals
CO2	Explain the method of preparation, assay, properties, medicinal uses of acids, bases, buffers, extra and intracellular electrolytes.
CO3	Explain the method of preparation, assay, properties, medicinal uses of dental products.
CO4	Explain the method of preparation, assay, properties, medicinal uses of acidifiers, antacids and cathartics.
CO5	Explain the method of preparation, assay, properties, medicinal uses of antimicrobials
CO6	Explain the method of preparation, assay, properties, medicinal uses of expectorants, emetics and haematinics
CO7	Explain the method of preparation, assay, properties, medicinal uses of astringent, poison and antidote
CO8	Describe the properties, storage condition and application of radiopharmaceuticals

Course Content:

UNIT – I	**10 Hours**
Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate **General methods of preparation**, assay for the compounds superscripted with **asterisk (*),** properties and medicinal uses of inorganic compounds belonging to the following classes	
UNIT – II	**10 Hours**
• **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity. • **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance. • **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.	
UNIT – III	**10 Hours**
• **Gastrointestinal agents** • **Acidifiers:** Ammonium chloride* and Dil. HCl • **Antacid:** Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture • **Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite • **Antimicrobials**: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations	
UNIT – IV	**08 Hours**
• **Miscellaneous compounds** **Expectorants:** Potassium iodide, Ammonium chloride*. **Emetics**: Copper sulphate*, Sodium potassium tartarate **]Haematinics:** Ferrous sulphate*, Ferrous gluconate **Poison and Antidote:** Sodium thiosulphate*, Activated charcoal, Sodium nitrite **Astringents**: Zinc Sulphate, Potash Alum	

UNIT – V	07 Hours
• **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.	

16BPH14P: PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I Limit tests for following ions

Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates Limit test for Iron
Limit test for Heavy metals Limit test for Lead
Limit test for Arsenic

II Identification test

Magnesium hydroxide Ferrous sulphate
Sodium bicarbonate Calcium gluconate Copper sulphate

III Test for purity

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV Preparation of inorganic pharmaceuticals

Boric acid Potash alum and Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

16BPH15: COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT I	**07 Hours**
• **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context • **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers • **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment	
UNIT II	**07 Hours**
• **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication	

• **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style	
UNIT III	**07 Hours**
• **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations • **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication • **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message	
UNIT IV	**05 Hours**
• **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview • **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery	
UNIT V	**04 Hours**
• **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion	

16BPH15P: COMMUNICATION SKILLS (Practical)

2 Hours / week

The following learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics
Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Don'ts

Pronunciations covering the following topics
Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)

Advanced Learning
Listening Comprehension / Direct and Indirect Speech
Figures of Speech
Effective Communication
Writing Skills
Effective Writing
Interview Handling Skills
E-Mail etiquette
Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success,

Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

16BPH16: REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

Course content:

UNIT I	**07 Hours**
Living world: • Definition and characters of living organisms • Diversity in the living world • Binomial nomenclature • Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus, **Morphology of Flowering plants** • Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed. • General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.	
UNIT II	**07 Hours**
Body fluids and circulation • Composition of blood, blood groups, coagulation of blood • Composition and functions of lymph • Human circulatory system • Structure of human heart and blood vessels • Cardiac cycle, cardiac output and ECG **Digestion and Absorption** • Human alimentary canal and digestive glands • Role of digestive enzymes • Digestion, absorption and assimilation of digested food **Breathing and respiration** • Human respiratory system	

• Mechanism of breathing and its regulation • Exchange of gases, transport of gases and regulation of respiration • Respiratory volumes	
UNIT III	**07 Hours**
Excretory products and their elimination • Modes of excretion • Human excretory system- structure and function • Urine formation • Rennin angiotensin system **Neural control and coordination** • Definition and classification of nervous system • Structure of a neuron • Generation and conduction of nerve impulse • Structure of brain and spinal cord • Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata **Chemical coordination and regulation** • Endocrine glands and their secretions • Functions of hormones secreted by endocrine glands **Human reproduction** • Parts of female reproductive system • Parts of male reproductive system • Spermatogenesis and Oogenesis • Menstrual cycle	
UNIT IV	**05 Hours**
Plants and mineral nutrition: • Essential mineral, macro and micronutrients • Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation **Photosynthesis** • Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.	
UNIT V	**04 Hours**
Plant respiration: Respiration, glycolysis, fermentation (anaerobic). **Plant growth and development** • Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators **Cell - The unit of life** • Structure and functions of cell and cell organelles.Cell division **Tissues** • Definition, types of tissues, location and functions	

Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C. Dutta.
d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

16BPH16P: REMEDIAL BIOLOGY (Practical)

2 Hours / week

1. Introduction to experiments in biology
    a) Study of Microscope
    b) Section cutting techniques
    c) Mounting and staining
    d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

16BPH17: REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT I	06 Hours
• **Partial fraction** Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics • **Logarithms** Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems. • **Function***:* Real Valued function, Classification of real valued functions, • **Limits and continuity** : Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1$,	

UNIT II	06 Hours
• **Matrices and Determinant:** Introduction matrices, types of matrices, operation on matrices, Pharmacokinetic equations Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations.	
UNIT III	**06 Hours**
• **Calculus** **Differentiation** : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n *w.r.t*x, where *n* is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x, Derivative of trigonometric functions from first principles **(without Proof)**, Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application	
UNIT IV	**06 Hours**
• **Analytical Geometry** **Introduction:** Signs of the Coordinates, Distance formula, **Straight Line** : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line **Integration:** Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application	

UNIT V	06 Hours
• **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations** • **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**	

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr. B.S. Grewal

II SEMESTER
16BPH21: HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Outcome

At the end of the course students will be able to...

CO1	Explain the anatomy, physiology and functions of various organs mentioned in chapters.
CO2	Understand the homeostatic mechanisms and altered physiology of nervous system.
CO3	Understand the homeostatic mechanisms and altered physiology of digestive system.
CO4	Understand the homeostatic mechanisms and altered physiology of respiratory and urinary system.
CO5	Understand the homeostatic mechanisms and altered physiology of endocrine system.

CO6	Understand the homeostatic mechanisms and altered physiology of reproductive system.
CO7	Apply the knowledge gained to understand the disease development and its progression.
CO8	Apply the basic knowledge gained by this course to understand the other disciplines of pharmacy

Course Content:

UNIT I	**10 Hours**
• **Nervous system** Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)	
UNIT II	**06 Hours**
• **Digestive system** Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT. • **Energetics** Formation and role of ATP, Creatinine Phosphate and BMR.	
UNIT III	**10 Hours**
• **Respiratory system** Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods. • **Urinary system** Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.	

UNIT IV	10 Hours
• **Endocrine system** Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.	
UNIT V	**09 Hours**
• **Reproductive system** Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition • **Introduction to genetics** Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance	

16BPH21P: HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.

5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

16BPH22: PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Outcome

At the end of the course students will be able to...

CO1	Describe the classification of organic compounds and nomenclature.
CO2	Classify isomerism and explain structural isomerism.
CO3	Explain hybridisation in alkenes, alkenes and stabilities of alkenes, conjugated dienes.
CO4	Explain the mechanism, orientation of elimination, Electrophilic, free radical and Nucleophilic addition reaction.
CO5	Discuss the mechanism, kinetics, stereochemistry and factors affecting SN_1 & SN_2 reaction.
CO6	Discuss the acidity of carboxylic acids and basicity of amines.
CO7	Discuss the mechanism of some named reaction.
CO8	Discuss the application, qualitative test and structure of organic compounds of medicinal importance.

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I	**07 Hours**
• **Classification, nomenclature and isomerism** Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerisms in organic compounds	
UNIT II	**10 Hours**
• **Alkanes*, Alkenes* and Conjugated dienes*** SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP^2 hybridization in alkenes E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation. Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement	
UNIT III	**10 Hours**
• **Alkyl halides*** SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations. SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform. • **Alcohols*-** Qualitative tests, Structure and uses of Ethyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol	
UNIT IV	**10 Hours**
• **Carbonyl compounds* (Aldehydes and ketones)** Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde	

UNIT V	08 Hours
• **Carboxylic acids*** Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid • **Aliphatic amines* -** Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine	

16BPH22P: PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
   a. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
   b. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
   c. Solubility test
   d. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
   e. Melting point/Boiling point of organic compounds
   f. Identification of the unknown compound from the literature using melting point/ boiling point.
   g. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
   h. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

16BPH23: BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shall able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Outcome

At the end of the course students will be able to...

CO1	Explain the concept of free energy and energy rich compounds
CO2	Describe the metabolism of carbohydrate molecule
CO3	Explain Electron transport chain, oxidative phosphorylation
CO4	Describe the metabolism of lipids in physiological and pathological condition.
CO5	Describe the metabolism of amino acids in physiological and pathological condition
CO6	Describe genetic organisation of mammalian genome, translation, replication, transcription and mutation.
CO7	Describe the metabolism of purine and pyramidine nucleotides in physiological and pathological condition
CO8	Describe the properties, classification, kinetics, inhibitors, importance of enzymes in diagnosis of diseases and therapeutic uses.

Course Content:

UNIT I	**04 Hours**
• **Bioenergetics** Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP	
UNIT II	**12 Hours**
• **Carbohydrate metabolism** Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus • **Biological oxidation** Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers	
UNIT III	**12 Hours**
• **Lipid metabolism** β-Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid) Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity. • **Amino acid metabolism** General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice	

UNIT IV	10 Hours
• **Nucleic acid metabolism and genetic information transfer** Biosynthesis of purine and pyrimidine nucleotides Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis Genetic code, Translation or Protein synthesis and inhibitors	
UNIT V	**07 Hours**
• **Enzymes** Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot) Enzyme inhibitors with examples Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions	

16BPH23P: BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley

16BPH24: PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course Outcome

At the end of the course students will be able to...

CO1	Describe Basic principles of Cell injury Adaptation and explain the concept of inflammation and repair
CO2	Describe the etiology and pathogenesis of various disorders pertaining to CVS, respiratory and renal system
CO3	classification, etiology and pathogenesis of cancer pertaining to Hematological, endocrine ,GI and nervous system
CO4	Classify and explain the etiology and pathogenesis of cancer
CO5	Describe the etiology and pathogenesis of disorders related to bones and joints
CO6	Describe the etiology and pathogenesis of Meningitis, Typhoid, Leprosy, Tuberculosis
CO7	Describe the etiology and pathogenesis of UTI
CO8	Describe the etiology and pathogenesis of AIDS, Syphilis, Gonorrhea

Course content:

UNIT I	**10 Hours**
• **Basic principles of Cell injury and Adaptation:** Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury**,** Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage)**,**Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia)**,** Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance • **Basic mechanism involved in the process of inflammation and repair:** Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis	
UNIT II	**10 Hours**
• **Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis) • **Respiratory system: Asthma, Chronic obstructive airways diseases.** • **Renal system: Acute and chronic renal failure**	
UNIT III	**10 Hours**
• **Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia • **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones • **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease. • **Gastrointestinal system:** Peptic Ulcer	
UNIT IV	**08 Hours**
• Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease. • **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout • **Principles of cancer:** classification, etiology and pathogenesis of cancer	
UNIT V	**07 Hours**
• **Infectious diseases: Meningitis, Typhoid, Leprosy,** Tuberculosis Urinary tract infections • **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea	

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw- Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online) Indian Journal of Pathology and Microbiology. ISSN-0377-4929

16BPH25: COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hours

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT I	**06 Hours**
Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division **Concept of I nformation Systems and Software : I**nformation gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project	
UNIT II	**06 Hours**
Web technologies: Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database	
UNIT III	**06 Hours**
Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System	

UNIT IV	**06 Hours**
Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery	
UNIT V	**06 Hours**
Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS)	

16BPH25P: COMPUTER APPLICATIONS IN PHARMACY (Practical)

2 Hours / Week

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3 Retrieve the information of a drug and its adverse effects using online tools
4 Creating mailing labels Using Label Wizard , generating label in MS WORD
5 Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

16BPH26: ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to**:**

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

UNIT I	**10 Hours**
The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.	
UNIT II	**10 Hours**
Ecosystems • Concept of an ecosystem. • Structure and function of an ecosystem. • Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)	
UNIT III	**10 Hours**
Environmental Pollution: Air pollution; Water pollution; Soil pollution	

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

III SEMESTER
16BPH31: PHARMACEUTICAL ORGANIC CHEMISTRY –II
(Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Outcome

At the end of the course students will be able to...

CO1	Explain the structure and uses of the organic compounds
CO2	Understand the reaction, name the reaction and orientation of reactions
CO3	Learn reactivity/stability of organic compounds
CO4	Learn the preparation of organic compounds
CO5	Understand the chemical reactions of organic compounds
CO6	Understand the principles/ mechanism of organic compounds
CO7	Understand the chemistry, chemical reactions and analytical constant of fats and oils
CO8	Understand the stability and chemical reactions of cycloalkanes

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I	10 Hours
• **Benzene and its derivatives** a. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule b. Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation. c. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction d. Structure and uses of DDT, Saccharin, BHC and Chloramine	
UNIT II	**10 Hours**
• **Phenols* -** Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols • **Aromatic Amines* -** Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts	
UNIT III	**10 Hours**
• **Fats and Oils** a. Fatty acids – reactions. b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils. c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.	
UNIT IV	**08 Hours**
• **Polynuclear hydrocarbons:** a. Synthesis, reactions b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives	
UNIT V	**07 Hours**
• **Cyclo alkanes*** Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only	

16BPH31P: PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques
- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)
- Acid value
- Saponification value
- Iodine value

III **Preparation of compounds**
- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- P-Iodo benzoic acid from P-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel’s text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz

16BPH32: PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and development

Course Outcome

At the end of the course students will be able to...

CO1	Understand the mechanisms of solute solvent interactions
CO2	Study the limitations and applications of Distribution law
CO3	Learn the steps involved in the preparation of pharmaceutical buffers and its importance
CO4	Study the use of physicochemical properties in formulation research and development
CO5	Acquire skills and working knowledge of the principles and concepts of surface tension and its measurement
CO6	Study the role of surfactants in various drug delivery applications
CO7	Understand the various intermolecular forces involved in the formation of complexes and its applications.
CO8	Understand the pharmaceutical applications of various techniques like lyophilisation

Course Content:

UNIT I	**10 Hours**
Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications	
UNIT II	**10 Hours**
States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism. **Physicochemical properties of drug molecules:** Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications	
UNIT III	**10 Hours**
Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.	
UNIT IV	**08 Hours**
Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.	
UNIT V	**07 Hours**
pH, buffers & Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.	

16BPH32P: PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory manual of physical pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

16BPH33: PHARMACEUTICAL MICROBIOLOGY (Theory)

45 Hours

Scope:

- Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

1 Understand methods of identification, cultivation and preservation of various microorganisms
2 To understand the importance and implementation of sterlization in pharmaceutical processing and industry
3 Learn sterility testing of pharmaceutical products.
4 Carried out microbiological standardization of Pharmaceuticals.
5 Understand the cell culture technology and its applications in pharmaceutical industries.

Course Outcome

At the end of the course students will be able to...

CO1	Understand the methods of identification, cultivation and preservation of various microorganisms such as bacteria, virus and fungi.
CO2	Define and classify the historical development and scope of microbiology.
CO3	Employ the knowledge to control the microbe by physical and chemical methods.
CO4	Understand the communicable diseases, sewage and sewage disposal, food spoilage and prevention of food from microbes.
CO5	Learn sterilization types and sterility testing of pharmaceutical products.
CO6	Demonstrate Microbiological standardization of Pharmaceutical products
CO7	Acquire knowledge in microbial spoilage of pharmaceutical products and sources and types of microbial contaminants in pharmaceutical products.
CO8	Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

UNIT I	**10 Hours**
Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.	
UNIT II	**10 Hours**
Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators	
UNIT III	**10 Hours**
Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP	
UNIT IV	**08 Hours**
Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.	

UNIT V	**07 Hours**
Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.	

16BPH33P: PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test (IMViC reactions)

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai

11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

16BPH34: PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course Outcome

At the end of the course students will be able to...

CO1	Know various unit operations used in Pharmaceutical industries.
CO2	Understand the various laws, mechanisms of unit operations.
CO3	Learn the various processes involved in Pharmaceutical manufacturing process.
CO4	Understand the material handling techniques.
CO5	Know the principle, construction, working, uses, advantages and disadvantages of Pharmaceutical equipments used for various unit operations.
CO6	Understand significance of plant layout design for optimum use of resources.
CO7	Know various preventive methods used for corrosion control in Pharmaceutical industries.
CO8	Understand the concepts of heat transfer and fluid flow.

Contents

UNIT I	**10 Hours**
• **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer. • **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill. • **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.	
UNIT II	**10 Hours**
• **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. • **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator. • **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation	
UNIT III	**10 Hours**
• **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer. • **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier.	
UNIT IV	**08 Hours**
• **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.	

• **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.	
UNIT V	**07 Hours**
• **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and its prevention. Ferrous and nonferrous metals, inorganic and organic non metals. Basic of Material handling systems.	

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

16BPH34P: PHARMACEUTICAL ENGINEERING (Practical)

4 Hrs/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.

II. Steam distillation – To calculate the efficiency of steam distillation.

III. To determine the overall heat transfer coefficient by heat exchanger.

IV. Construction of drying curves (for calcium carbonate and starch).

V. Determination of moisture content and loss on drying.

VI. Determination of humidity of air – i) From wet and dry bulb temperatures – use of Dew point method.

VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.

VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.

IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.

X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.

XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity

XII. To study the effect of time on the Rate of Crystallization.

XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

IV SEMESTER

16BPH41: PHARMACEUTICAL ORGANIC CHEMISTRY – III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Outcome

At the end of the course students will be able to...

CO1	Understand the methods of preparation and properties of organic compounds
CO2	Explain the stereo chemical aspects of organic compounds and stereo chemical reaction
CO3	Know the medicinal uses and other applications of organic compounds
CO4	Understand the important named reactions
CO5	Understand the nomenclature of organic compounds
CO6	Understand the basic terminologies in stereochemistry and organic reactions
CO7	Understand the properties of heterocyclic compounds
CO8	Understand the aromaticity and reactivity of heterocyclic compounds

Course Content:

UNIT I	**10 Hours**
Stereo isomerism Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute	
UNIT II	**10 Hours**
Geometrical isomerism Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers. Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions	
UNIT III	**10 Hours**
Heterocyclic compounds Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene Relative aromaticity, reactivity of Pyrrole, Furan and Thiophene	
UNIT IV	**08 Hours**
Synthesis, reactions and medicinal uses of following compounds / derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives	
UNIT V	**07 Hours**
Reactions of synthetic importance Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation	

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

16BPH42: MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship (SAR) of different class of drugs
4. Write the chemical synthesis of some drugs

Course Outcome

At the end of the course students will be able to...

CO1	Explain the various physiochemical properties in relation to biological activity
CO2	Discuss drug metabolism
CO3	Study SAR of some important drug classes and mode of action at molecular level.
CO4	Learn pharmacological action of different drug classes and their Side effects
CO5	Learn synthesis of the important class of compounds
CO6	Explain drugs acting on the adrenergic nervous system and cholinergic nervous system
CO7	Discuss the drugs acting as CNS depressants: Anticonvulsants, Antipsychotics, Sedatives & Hypnotics
CO8	Learn drugs acting on CNS: Local anaesthetics, antihistamines, analgesics & anti-inflammatory agents.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT I	**10 Hours**
Introduction to Medicinal Chemistry **History and development of medicinal chemistry** **Physicochemical properties in relation to biological action** Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism. **Drug metabolism** Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism.	
UNIT II	**10 Hours**
Drugs acting on Autonomic Nervous System **Adrenergic Neurotransmitters:** Biosynthesis and catabolism of catecholamines. Adrenergic receptors (Alpha & Beta) and their distribution. **Sympathomimetic agents: SAR of Sympathomimetic agents** Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Naphazoline, Oxymetazoline and Xylometazoline. • Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine. • Agents with mixed mechanism: Ephedrine, Metaraminol. **Adrenergic Antagonists:** **Alpha adrenergic blockers:** Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide. **Beta adrenergic blockers:** SAR of beta blockers, Propranolol*, Atenolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol	
UNIT III	**10 Hours**
Cholinergic neurotransmitters: Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.	

Parasympathomimetic agents: SAR of Parasympathomimetic agents **Direct acting agents:** Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine. **Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):** Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide. **Cholinesterase reactivator:** Pralidoxime chloride. **Cholinergic Blocking agents: SAR of cholinolytic agents** **Solanaceous alkaloids and analogues:** Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*. **Synthetic cholinergic blocking agents:** Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Propantheline bromide, Benztropine mesylate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride.	
UNIT IV	**08 Hours**
Drugs acting on Central Nervous System **A. Sedatives and Hypnotics:** **Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem **Barbiturtes:** SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital **Miscelleneous:** Amides & imides: Glutethmide. Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde. **B. Antipsychotics** **Phenothiazeines:** SAR of Phenothiazeines - Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride. **Ring Analogues of Phenothiazeines: Chlorprothixene**, Thiothixene, Loxapine succinate, Clozapine. **Fluro buterophenones:** Haloperidol, Droperidol, Risperidone. **Beta amino ketones:** Molindone hydrochloride. **Benzamides:** Sulpieride. **C. Anticonvulsants:** SAR of Anticonvulsants**,** mechanism of anticonvulsant action **Barbiturates**: Phenobarbitone, Methabarbital. **Hydantoins:**Phenytoin*, Mephenytoin, Ethotoin	

Oxazolidine diones: Trimethadione, Paramethadione **Succinimides:** Phensuximide, Methsuximide, Ethosuximide* **Urea and monoacylureas**: Phenacemide, Carbamazepine* **Benzodiazepines**: Clonazepam **Miscellaneous:** Primidone, Valproic acid , Gabapentin, Felbamate	
UNIT V	**07 Hours**
Drugs acting on Central Nervous System General anesthetics: **Inhalation anesthetics:** Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. **Ultra short acting barbitutrates:** Methohexital sodium*, Thiamylal sodium, Thiopental sodium. **Dissociative anesthetics:** Ketamine hydrochloride.* **Narcotic and non-narcotic analgesics** **Morphine and related drugs:** SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate, Tramadot. **Narcotic antagonists:** Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride. **Anti-inflammatory agents:** Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Acetaminophen, Phenylbutazone.	

16BPH42P: MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

1. 1,3-pyrazole
2. 1,3-oxazole
3. Benzimidazole
4. Benztriazole
5. 2,3- diphenyl quinoxaline
6. Benzocaine
7. Phenytoin
8. Phenothiazine
9. Barbiturate

II Assay of drugs

1. Chlorpromazine
2. Phenobarbitone
3. Atropine
4. Ibuprofen
5. Aspirin
6. Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel

16BPH43: PHYSICAL PHARMACEUTICS-II (Theory)

45 Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Outcome

At the end of the course students will be able to...

CO1	Learn the formulation concepts of pharmaceutical suspensions and emulsions and their stability problems
CO2	Acquire working knowledge and understanding the concepts of colloids and its applications
CO3	Study the reaction kinetics, reaction order, factors affecting the rate of the reactions
CO4	Have basic understanding of degradation and stabilization of medicinal agents as well as accelerated stability testing.
CO5	Understand the flow behaviour of fluids and also to identify suitable characteristics for each formulations
CO6	Study the different types of deformation of solids and stress-strain relationship
CO7	Explain the derived properties and flow properties of powders and its role in formulation development
CO8	Know the methods to determine particle size and its role in formulation development

Course Content:

UNIT I	**07 Hours**
Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action.	
UNIT II	**08 Hours**
Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers **Deformation of solids:** Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus	
UNIT III	**10 Hours**
Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.	
UNIT IV	**10 Hours**
Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.	
UNIT V	**10 Hours**
Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention	

16BPH43P: PHYSICAL PHARMACEUTICS- II (Practical)

4 Hrs/week

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R

16BPH44: PHARMACOLOGY-I (Theory)

45 Hours

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Outcome

At the end of the course students will be able to...

CO1	Describe the history and scope of pharmacology
CO2	Explain general pharmacological concepts such as pharmacodynamics and pharmacokinetics
CO3	Describe drug discovery and clinical evaluation of new drugs
CO4	Explain neurotransmission and the role of neurotransmitters
CO5	Explain the different Classes of drugs acting on sympathetic and parasympathetic system
CO6	Explain the types of drug receptors and their signalling mechanism
CO7	Explain the different Classes of drugs used in various CNS disorders like anxiety, depression, mania, parkinsonism and Alzheimer's
CO8	Explain the concept of drug addiction, drug tolerance , drug abuse , drug interactions and Pharmacovigilance

Course Content:

UNIT I	**08 Hours**
General Pharmacology **a.** Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. **b.** Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination	
UNIT II	**12 Hours**
General Pharmacology a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. b. Adverse drug reactions. c. Drug interactions (pharmacokinetic and pharmacodynamic) d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.	
UNIT III	**10 Hours**
Pharmacology of drugs acting on peripheral nervous system a.Organization and function of ANS. b. Neurohumoral transmission, co-transmission and classification of neurotransmitters. c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics. d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). e. Local anesthetic agents. f. Drugs used in myasthenia gravis and glaucoma	

UNIT IV	08 Hours
Pharmacology of drugs acting on central nervous system a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine. b. General anesthetics and pre-anesthetics**.** c. Sedatives, hypnotics and centrally acting muscle relaxants. d. Anti-epileptics e. Alcohols and disulfiram	
UNIT V	**07 Hours**
Pharmacology of drugs acting on central nervous system a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens. b. Drugs used in Parkinsons disease and Alzheimer's disease. c. CNS stimulants and nootropics. d. Opioid analgesics and antagonists e. Drug addiction, drug abuse, tolerance and dependence.	

16BPH44P: PHARMACOLOGY-I (Practical)

4Hours / Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: *All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology. Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

16BPH45: PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. To know the techniques in the cultivation and production of crude drugs
2. To know the crude drugs, their uses and chemical nature
3. Know the evaluation techniques for the herbal drugs
4. To carry out the microscopic and morphological evaluation of crude drugs

Course Outcome

At the end of the course students will be able to...

CO1	Discuss the definition, history, scope and development of pharmacognosy
CO2	Describe the techniques in the cultivation, processing, storage and production of crude drugs of natural origin
CO3	Describe fundamental aspects of plant tissue culture
CO4	Describe different types of secondary metabolites, their general properties, classification, and their test for identification
CO5	Describe the sources, chemical constituents and uses of plants products containing plant fibers, hallucinogens teratogens, and natural allergens
CO6	Describe the pharmacognosy and chemistry of primary metabolites (carbohydrates, lipids, proteins) and elaborate on their sources
CO7	Describe novel medicinal agents from marine sources
CO8	Describe the role of Pharmacognosy in allopathy and traditional system of medicine

Course Content:

UNIT I	**10 Hours**
Introduction to Pharmacognosy: (a) Definition, history, scope and development of Pharmacognosy (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins). **Classification of drugs:** Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs **Quality control of Drugs of Natural Origin:** Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.	
UNIT II	**10 Hours**
Cultivation, Collection, Processing and storage of drugs of natural origin: Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants **Conservation of medicinal plants**	
UNIT III	**07 Hours**
Plant tissue culture: Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines	
UNIT IV	**10 Hours**
Pharmacognosy in various systems of medicine: Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine. **Introduction to secondary metabolites:** Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins	

UNIT V	08 Hours
Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs **Plant Products:** Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens **Primary metabolites:** General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites: **Carbohydrates:** Acacia, Agar, Tragacanth, Honey **Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin). **Lipids(Waxes, fats, fixed oils)** : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax **Marine Drugs:** Novel medicinal agents from marine sources	

16BPH45P: PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and paliside ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

V SEMESTER
16BPH51: MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Outcome

At the end of the course students will be able to...

CO1	Learn SAR of some important drug classes and mode of action at molecular level.
CO2	Learn pharmacological action of different drug classes and their side effects
CO3	Explain synthesis of important class of compounds
CO4	Describe drugs used as Anti histamines, anti diabetic agents & cytotoxic agents
CO5	Understand drugs acting on Cardiovascular systems:Anti-anginal, Vasodilators, Calcium channel blockers, Diuretics
CO6	Learn Anti-hypertensive Agents,Anti-arrhythmic Drugs Anti-hyperlipidemic agents Coagulant & Anticoagulants, Drugs used in Congestive Heart Failure
CO7	Understand drugs acting on Endocrine system:Sexhormones, Drugs for erectile dysfunction Oral contraceptives, Corticosteroids,Thyroid and antithyroid drugs
CO8	Learn Drugs used as Local anesthetics & anti thyroid gents

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT I	**10 Hours**
Antihistaminic agents: Histamine, receptors and their distribution in the human body **H_1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenyl phyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine, Cromolyn sodium **H_2-antagonists:** Cimetidine*, Famotidine, Ranitidin. **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole **Anti-neoplastic agents:** **Alkylating agents:** Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa **Antimetabolites:** Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine **Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin **Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate **Miscellaneous:** Cisplatin, Mitotane	
UNIT II	**10 Hours**
Anti-anginal: **Vasodilators:** Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole. **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.	

Diuretics: Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol **Anti-hypertensive Agents**: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.	
UNIT III	**10 Hours**
Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol. **Anti-hyperlipidemic agents**: Clofibrate, Lovastatin, Cholesteramine and Cholestipol **Coagulant & Anticoagulants**: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel **Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan	
UNIT IV	**08 Hours**
Drugs acting on Endocrine system Nomenclature, Stereochemistry and metabolism of steroids **Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol. **Drugs for erectile dysfunction:** Sildenafil, Tadalafil. **Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone **Thyroid and antithyroid drugs**: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	

UNIT V	07 Hours
Antidiabetic agents: Insulin and its preparations Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acrabose, Voglibose. **Local Anesthetics:** SAR of Local anesthetics **Benzoic Acid derivatives**; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. **Amino Benzoic acid derivatives**: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate. **Lidocaine/Anilide derivatives**: Lignocaine, Mepivacaine, Prilocaine, Etidocaine. **Miscellaneous**: Phenacaine, Diperodon, Dibucaine.*	

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

16BPH52: INDUSTRIAL PHARMACY- I (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course Outcome

At the end of the course students will be able to...

CO1	Carry out assessment of physicochemical properties of drugs as a tool in the optimization of solid and liquid dosage forms
CO2	Formulate and prepare tablets, capsules and liquid orals using established procedures and technology.
CO3	Describe the facilities and standards necessary for the industrial production of sterile dosage forms.
CO4	Formulate and prepare different types of parenteral and ophthalmic dosage forms
CO5	Evaluate the pharmaceutical dosage forms for quality and stability and compare with standards prescribed in the pharmacopoeia
CO6	Select ingredients and formulate cosmetics such as lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens
CO7	Identify containers, closures, valves and propellants for different types of aerosol systems.
CO8	Select and evaluate appropriate packaging materials for various pharmaceutical dosage forms.

Course content:

UNIT I	**07 Hours**
Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. ***a. Physical properties:*** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism ***b.Chemical Properties:*** Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	
UNIT II	**10 Hours**
Tablets: a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. Quality control tests: In process and finished product tests **Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia	
UNIT III	**08 Hours**
Capsules: ***a.*** **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules. ***b.*** **Soft Galatin capsules**: Nature of shell and capsule content, size of capsules,importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. **Pellets:**Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets	

UNIT IV	10 Hours
Parenteral Products: a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity b. Production procedure, production facilities and controls, aseptic processing c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized product. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of perentaral products. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations	
UNIT V	**10 Hours**
Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. **Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. **Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.	

16BPH52P: INDUSTRIAL PHARMACY- I (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

16BPH53: PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student shall be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Outcome

At the end of the course students will be able to...

CO1	Describe the different classes of drugs used in the treatment of diseases pertaining to cardio-vascular system
CO2	Classify diuretics ,anti diuretics and Explain their Pharmacology
CO3	Explain the Pharmacology of Haematinics, coagulants & anti coagulants, fibrinolytics and antiplatelet drugs
CO4	Describe the Pharmacotherapy of Shock and explain plasma volume expanders
CO5	Explain the mechanism of drug action in the treatment of diseases pertaining to endocrine system
CO6	Describe the pharmacology of autocoids and related drugs
CO7	Discuss the principle, types of bioassays and methods of bio-assay of insulin, oxytoxin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT
CO8	Describe the Pharmacology of male and female sex hormones and explain oral contraceptives

Course Content:

UNIT I	**10 Hours**
Pharmacology of drugs acting on cardio vascular system a. Introduction to hemodynamic and electrophysiology of heart. b. Drugs used in congestive heart failure c. Anti-hypertensive drugs. d. Anti-anginal drugs. e. Anti-arrhythmic drugs. f. Anti-hyperlipidemic drugs	
UNIT II	**10 Hours**
Pharmacology of drugs acting on cardio vascular system a. Drug used in the therapy of shock. b. Hematinics, coagulants and anticoagulants. c. Fibrinolytics and anti-platelet drugs d. Plasma volume expanders **Pharmacology of drugs acting on urinary system** e. Diuretics f. Anti-diuretics.	
UNIT III	**10 Hours**
Autocoids and related drugs a. Introduction to autacoids and classification b. Histamine, 5-HT and their antagonists. c. Prostaglandins, Thromboxanes and Leukotrienes. d. Angiotensin, Bradykinin and Substance P. e. Non-steroidal anti-inflammatory agents f. Anti-gout drugs g. Antirheumatic drugs	
UNIT IV	**08 Hours**
Pharmacology of drugs acting on endocrine system a. Basic concepts in endocrine pharmacology. b. Anterior Pituitary hormones- analogues and their inhibitors. c. Thyroid hormones- analogues and their inhibitors. d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. e. Insulin, Oral Hypoglycemic agents and glucagon. f. ACTH and corticosteroids.	

UNIT V	07 Hours
Pharmacology of drugs acting on endocrine system a. Androgens and Anabolic steroids. b. Estrogens, progesterone and oral contraceptives. c. Drugs acting on the uterus. **Bioassay** d. Principles and applications of bioassay. e. Types of bioassay f. Bioassay of insulin, oxytocin, vasopressin, ACTH, d- tubocurarine, digitalis, histamine and 5-HT	

16BPH53P: PHARMACOLOGY-II (Practical)

4Hours / Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: *All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

16BPH54: PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. To understand the preparation and development of herbal formulation.
3. To understand the herbal drug interactions
4. To carryout isolation and identification of phytoconstituents

Course Outcome

At the end of the course students will be able to...

CO1	Explain basic metabolic pathways of plants and formation of different secondary metabolites through various biosynthetic pathways in plants
CO2	Describe utilization of radioactive isotopes in the investigation of biosynthetic pathways
CO3	Explain source, chemistry, therapeutic uses of various secondary metabolites containing drugs.
CO4	Describe methods of extraction, analysis and commercial application of various secondary metabolites containing drugs.
CO5	Describe methods for industrial production, estimation and utilization of some therapeutically important phytoconstituents
CO6	Describe various modern methods for extraction
CO7	Application of latest techniques for analysis of phytoconstituents
CO8	Explain the process of isolation, purification and identification of crude drugs

Course Content:

UNIT I	**07 Hours**
Metabolic pathways in higher plants and their determination a)Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. b)Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.	
UNIT II	**14 Hours**
General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites: **Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium, **Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta **Steroids, Cardiac Glycosides & Triterpenoids**: Liquorice, Dioscorea, Digitalis **Volatile oils**: Mentha, Clove, Cinnamon, Fennel, Coriander **Tannins:** Catechu, Pterocarpus **Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony **Glycosides:** Senna, Aloes, Bitter Almond **Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids	
UNIT III	**06 Hours**
Isolation, Identification and Analysis of Phytoconstituents a) Terpenoids: Menthol, Citral, Artemisin b) Glycosides: Glycyrhetinic acid & Rutin c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine d) Resins: Podophyllotoxin, Curcumin	
UNIT IV	**10 Hours**
Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine	

UNIT IV	08 Hours
Basics of Phytochemistry Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.	

16BPH54P: PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
    a. Caffeine - from tea dust.
    b. Diosgenin from Dioscorea
    c. Atropine from Belladonna
    d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests:
    (i) Asafoetida
    (ii) Benzoin
    (iii) Colophony
    (iv) Aloes
    (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

16BPH55: PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Outcome

At the end of the course students will be able to...

CO1	Understand the pharmaceutical legislation and implications in the development and marketing of pharmaceuticals
CO2	Know Different Pharmaceutical acts, laws and rules
CO3	Know the regulatory and administrative authorities, agencies governing manufacture and sale of pharmaceuticals
CO4	Know the regulations of DPCO-2013
CO5	Understand the CPSCEA guidelines for Prevention of cruelty to animals act
CO6	Understand the concept of medical termination of pregnancy act
CO7	Understand the concept of Intellectual property rights and Right to information act
CO8	Know the codes of Pharmaceutical ethics during the pharmaceutical practice

Course Content:

UNIT I	10 Hours
Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the act and rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties**.** Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	
UNIT II	**10 Hours**
Drugs and Cosmetics Act, 1940 and its rules 1945. Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	
UNIT III	**10 Hours**
• **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and Penalties • **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties. • **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	

UNIT IV	08 Hours
• **Study of Salient Features of Drugs and magic remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties • **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled • formulations, National List of Essential Medicines (NLEM)	

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

VI SEMESTER
16BPH61: MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Outcome

At the end of the course students will be able to...

CO1	Definition, Classification of the drugs with examples and structures
CO2	Explain the Drugs used for various infectious diseases caused by pathogens
CO3	Describe the structure activity relation of some important class of drugs
CO4	Explain mechanism of action of the drugs
CO5	Describe synthesis of medicinally important drug
CO6	Explain Therapeutic uses of drugs and Specific side effect of 'Drug Substances'
CO7	Explain physico chemical properties related to QSAR
CO8	Describe various approaches and designing of drug molecules including prodrug and Combinatorial chemistry

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT I	**10 Hours**
Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin, Gentaneycin **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	
UNIT II	**10 Hours**
Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes **Macrolide:** Erythromycin Clarithromycin, Azithromycin. **Miscellaneous:** Chloramphenicol*, Clindamycin. **Prodrugs:** Basic concepts and application of prodrugs design. **Antimalarials:** Etiology of malaria. **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil. **Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone	
UNIT III	**10 Hours**
Anti-tubercular Agents Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* **Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.	

Urinary tract anti-infective agents **Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine. Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir	
UNIT IV	**08 Hours**
Antifungal agents: **Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin. **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoal Agents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin **Sulphonamides and Sulfones** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine. **Folate reductase inhibitors:** Trimethoprim*, Cotrimoxazole. **Sulfones:** Dapsone*	

UNIT V	07 Hours
Introduction to Drug Design Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis	

16BPH61P: MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol
4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine

II Assay of drugs

1. Isonicotinic acid hydrazide
2. Chloroquine
3. Metronidazole
4. Dapsone
5. Chlorpheniramine maleate
6. Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I. Vogel.

16BPH62: PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student shall be able to:

1. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. Comprehend the principles of toxicology and treatment of various poisonings and
3. Appreciate correlation of pharmacology with related medical sciences.

Course Outcome

At the end of the course students will be able to...

CO1	Describe pharmacology of drugs acting on respiratory, and GI system.
CO2	Explain chemotherapy of specific infection and infestations.
CO3	Classification of drugs acting on immunity.
CO4	Describe pharmacology of anticancer agents.
CO5	Describe management of toxicity by barbiturates, benzodiapines, alcohol intoxication
CO6	Describe management of toxicity by morphine, organo phosphosphorus compounds, lead, mercury and arsenic poisoning.
CO7	Explain significance of chronotherapy.
CO8	Explain the pharmacology of immune stimulants and Immuno suppressants.

Course Content:

UNIT I	10 Hours
1.Pharmacology of drugs acting on Respiratory system a. Anti -asthmatic drugs b. Drugs used in the management of COPD c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants **2.Pharmacology of drugs acting on the Gastrointestinal Tract** a.Antiulcer agents. b.Drugs for constipation and diarrhoea. c.Appetite stimulants and suppressants. d.Digestants and carminatives. e.Emetics and anti-emetics.	
UNIT II	**10 Hours**
3. Chemotherapy a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics - Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	
UNIT III	**10 Hours**
4. Chemotherapy a. Antitubercular agents b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e. Anthelmintics f. Antimalarial drugs g. Antiamoebic agents	
UNIT IV	**08 Hours**
5. Chemotherapy a) Urinary tract infections and sexually transmitted diseases. b) Chemotherapy of malignancy. **6. Immunopharmacology** a. Immunostimulants b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	

UNIT V	07 Hours
7. Principles of toxicology **a.** Definition and basic knowledge of acute, subacute and chronic toxicity. **b.** Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity **c.** General principles of treatment of poisoning **d.** Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning. **8. Chronopharmacology** a. Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy	

16BPH62P: PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligation (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology

16BPH63: HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs.

Objectives: Upon completion of this course the student shall be able to:

1. Understand raw material as source of herbal drugs from cultivation to herbal drug product
2. Know the WHO and ICH guidelines for evaluation of herbal drugs
3. Know the herbal cosmetics, natural sweeteners, nutraceuticals
4. Appreciate patenting of herbal drugs, GMP

Course Outcome

At the end of the course students will be able to...

CO1	Explain method for identification and authentication of herbal drugs
CO2	Explain methods for selection and processing of herbal drugs as raw materials for herbal drug preparation
CO3	Explain methods of good agricultural practices for medicinal plants like organic farming and using biopesticides for pest control
CO4	Explain basic principles of traditional medicinal systems with method of preparation and standardization of ayurvedic formulations
CO5	Describe benefits of various plants as nutraceuticals in ailments and also the herb-food interaction of various plant drugs
CO6	Describe about herbs or natural origin drugs as raw materials for preparation of cosmetics, excipients, conventional herbal formulation and novel dosage forms like phytosomes
CO7	Describe rules and regulation for assessment of herbal drugs, patenting of natural products and manufacture of herbal formulations based on traditional medicinal system.

CO8	Explain present status and prospects of herbal drug based industry and components for Good Manufacturing Practice for Indian systems of medicine

Course content:

UNIT I	**11 Hours**
Herbs as raw materials Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs, Selection, identification and authentication of herbal materials Processing of herbal raw material **Biodynamic Agriculture** Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides / Bioinsecticides **Indian Systems of Medicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma	
UNIT II	**07 Hours**
Nutraceuticals General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.	

UNIT III	10 Hours
Herbal Cosmetics Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products. **Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes. **Herbal formulations:** Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes	
UNIT IV	**10 Hours**
Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem. **Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.	
UNIT V	**07 Hours**
General Introduction to Herbal Industry Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. **Schedule T – Good Manufacturing Practice of Indian systems of medicine** Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.	

16BPH63P: HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H. Ansari
5. Pharmacognosy & Phytochemistry by V.D. Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

16BPH64: BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arises therein.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications

Course Outcome

At the end of the course students will be able to...

CO1	Carry out biopharmaceutical studies and use data so obtained in the development of new drugs or dosage forms.
CO2	Determine the factors that affect absorption, distribution, metabolism and excretion of drugs and the mechanisms involved in these processes.
CO3	Evaluate drug-protein binding as a tool to predict pharmacokinetics of drugs.
CO4	Select the correct pharmacokinetic model based on plasma level or urinary excretion data that best describes the process of drug absorption, distribution, metabolism and elimination (ADME).
CO5	Calculate various pharmacokinetic parameters from plasma and urinary excretion data applying compartment modeling and model independent methods to describe the kinetics of drug absorption, distribution, metabolism, excretion or elimination
CO6	Design dosage regimens for patients based on calculated pharmacokinetic parameters.

CO7	Design Bioavailability and Bioequivalence studies of new drugs or dosage forms.
CO8	Estimate pharmacokinetic parameters for drugs that undergo non – linear pharmacokinetics

Course Content:

UNIT I	**10 Hours**
Introduction to Biopharmaceutics **Absorption**; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra- vascular routes **Distribution**: Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs	
UNIT II	**10 Hours**
Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs. **Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs	
UNIT III	**10 Hours**
Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE, t1/2, Vd, AUC, Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application	
UNIT IV	**08 Hours**
Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenace doses and their significance in clinical settings.	

UNIT V	07 Hours
Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity c. Michaelis - menton method of estimating parameters, Biotransformation of drugs	

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

16BPH65: PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Course Outcome

At the end of the course students will be able to...

CO1	Acquire knowledge in basic principles of genetic engineering and enzyme technology
CO2	Apply the principles of biosensors and protein engineering in Pharmaceutical Industry
CO3	Explain the concepts of rDNA technology and its applications
CO4	Describe the concept of immunity and production of vaccine
CO5	Define hybridoma technology and understand hypersensitivity reaction
CO6	Knowledge on genetic multiplication and biotransformation
CO7	Discuss the principles of fermentation its design and production of pharmaceutical products
CO8	Describe various blood products, plasma collection and processing of it.

Course Contents

UNIT I	**10 Hours**
a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme Biotechnology- Methods of enzyme immobilization and applications. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries. d) Brief introduction to Protein Engineering. e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering	
UNIT II	**10 Hours**
a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of rDNA technology and genetic engineering in the products: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones- Insulin. d) Brief introduction to PCR Types of immunity- humoral immunity, cellular immunity	
UNIT III	**10 Hours**
Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substitutes	

UNIT IV	08 Hours
a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation / mutants	
UNIT V	**07 Hours**
a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties	

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

16BPH66: PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

Course Outcome

At the end of the course students will be able to...

CO1	Understand the pharmaceutical legislation and implications in the development and marketing of pharmaceuticals
CO2	Know Different Pharmaceutical acts, laws and rules
CO3	Know the regulatory and administrative authorities, agencies governing manufacture and sale of pharmaceuticals
CO4	Know the regulations of DPCO-2013
CO5	Understand the CPSCEA guidelines for Prevention of cruelty to animals act
CO6	Understand the concept of medical termination of pregnancy act
CO7	Understand Concept of Intellectual property rights and Right to information act
CO8	Know the codes of Pharmaceutical ethics during the pharmaceutical practice

Course content

UNIT I	**10 Hours**
Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines**: Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD)**: Definition, overview, elements of QbD program, tools **ISO 9000 & ISO 14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation** : Principles and procedure	
UNIT II	**10 Hours**
Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. **Equipments and raw materials:** Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials	
UNIT III	**10 Hours**
Quality Control: Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	
UNIT IV	**08 Hours**
Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	

UNIT V	07 Hours
Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management	

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

VII SEMESTER
16BPH71: INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Outcome

At the end of the course students will be able to...

CO1	Explain the theoretical principles of UV and IR spectroscopy.
CO2	Learn basic principles and instrumentation of UV, IR, fluorimeter, flame photometer.
CO3	Learn basic principles involved in TLC, column chromatography and paper chromatography
CO4	Understand the separation of compounds by chromatographic techniques.
CO5	Explain Instrumentation, separation and identification of compounds by electrophoresis technique.
CO6	Learn separation and identification of compounds by various chromatographic techniques.
CO7	Explain theory and instrumentation of GC, HPLC, gel chromatography, ion exchange chromatography and affinity chromatography.
CO8	Learn applications of various chromatographic techniques for organic, inorganic and natural products.

Course Content

UNIT I	**10 Hours**
UV Visible spectroscopy Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component analysis **Fluorimetry** Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications	
UNIT II	**10 Hours**
IR spectroscopy Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations **Instrumentation** - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications **Flame Photometry-**Principle, interferences, instrumentation and applications **Atomic absorption spectroscopy**- Principle, interferences, instrumentation and applications **Nepheloturbidometry**- Principle, instrumentation and applications	
UNIT III	**10 Hours**
Introduction to chromatography **Adsorption and partition column chromatography -** Methodology, advantages, disadvantages and applications. **Thin layer chromatography -** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications. **Paper chromatography -** Introduction, methodology, development techniques, advantages, disadvantages and applications **Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications	

UNIT IV	08 Hours
Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications **High performance liquid chromatography (HPLC) -** Introduction, theory, instrumentation, advantages and applications	
UNIT V	**07 Hours**
Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications **Gel chromatography-** Introduction, theory, instrumentation and applications **Affinity chromatography-**Introduction, theory, instrumentation and applications	

16BPH71P: INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2 Estimation of dextrose by colorimetry
3 Estimation of sulfanilamide by colorimetry
4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5 Assay of paracetamol by UV- Spectrophotometry
6 Estimation of quinine sulfate by fluorimetry
7 Study of quenching of fluorescence
8 Determination of sodium by flame photometry
9 Determination of potassium by flame photometry
10 Determination of chlorides and sulphates by nephelo turbidometry
11 Separation of amino acids by paper chromatography
12 Separation of sugars by thin layer chromatography
13 Separation of plant pigments by column chromatography
14 Demonstration experiment on HPLC
15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

16BPH72: INDUSTRIAL PHARMACY II (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Outcome

At the end of the course students will be able to...

CO1	Discuss the process of pilot plant scale up of pharmaceutical dosage forms.
CO2	Demonstrate the practice and the process of technology transfer from lab scale to commercial.
CO3	Explain the different laws and acts that regulate pharmaceutical industry.
CO4	Describe the approval process and regulatory requirements of drug products.
CO5	Describe the common measure use in quality.
CO6	Describe the role and responsibility of regulatory agencies in the approval of drugs.
CO7	Describe the organization and responsibilities of national and state licensing authority.
CO8	Discuss the guidelines for technology transfer.

Course Content

UNIT I	**10 Hours**
Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology	
UNIT II	**10 Hours**
Technology development and transfer: WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	
UNIT III	**10 Hours**
Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies	
UNIT IV	**08 Hours**
Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	

UNIT V	07 Hours
Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs	

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. Available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm

16BPH73: PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the student shall be able to

1. Know various drug distribution methods in a hospital
2. Appreciate the pharmacy stores management and inventory control
3. Monitor drug therapy of patient through medication chart review and clinical review
4. Obtain medication history interview and counsel the patients
5. Identify drug related problems
6. Detect and assess adverse drug reactions
7. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. Know pharmaceutical care services
9. Do patient counseling in community pharmacy;
10. Appreciate the concept of Rational drug therapy.

Course Outcome

At the end of the course students will be able to...

CO1	Describe the functioning of hospital pharmacy. Identify and assess adverse drug reactions. Describe the functioning of community pharmacy
CO2	Recognize various drug distribution system in the hospital
CO3	Develop the contents of hospital formulary
CO4	Practice patient medication history interview and patient counseling

CO5	Describe the functioning of pharmacy and therapeutic committee.
CO6	Describe the functions and responsibilities of clinical pharmacist
CO7	Explain drug store management and inventory control
CO8	Interpret clinical laboratory tests of specific disease states

Course Content

UNIT I	**10 Hours**
a) Hospital and it's organization Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. **b) Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **c) Adverse drug reaction** Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detectingdrug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. **d) Community Pharmacy** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.	
UNIT II	**10 Hours**
a) Drug distribution system in a hospital Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.	

b) Hospital formulary Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary. **c) Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. **d) Medication adherence** Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. **e) Patient medication history interview** Need for the patient medication history interview, medication interview forms. **f) Community pharmacy management** Financial, materials, staff, and infrastructure requirements.	
UNIT III	**10 Hours**
a) Pharmacy and therapeutic committee Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. **b) Drug information services** Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. **c) Patient counseling** Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist **d) Education and training program in the hospital** Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. **e) Prescribed medication order and communication skills** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients	

UNIT IV	08 Hours
a) Budget preparation and implementation Budget preparation and implementation **b) Clinical Pharmacy** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. **c) Over the counter (OTC) sales** Introduction and sale of over the counter, and Rational use of common over the counter medications.	
UNIT V	**07 Hours**
a) Drug store management and inventory control Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure **b) Investigational use of drugs** Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee. **c) Interpretation of Clinical Laboratory Tests** Blood chemistry, hematology, and urine analysis	

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.

6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

16BPH74: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course Outcome

At the end of the course students will be able to...

CO1	Explain the principles and technology used in the design of sustained release and controlled release drug delivery systems
CO2	Learn the criteria for selection of a drugs and polymers for the development of Novel drug delivery systems
CO3	Learn the various approaches for development of novel drug delivery systems.
CO4	Explain the formulation and evaluation of Novel drug delivery systems
CO5	Explain the formulation and characterization of transdermal drug Delivery systems
CO6	Learn the formulation and evaluation of Gastroretentive & Nasopulmonary drug delivery systems
CO7	Discuss various approaches for the development of targeted drug Delivery systems
CO8	Explain development of ocular formulations and intra uterine devices (IUDs) and it's applications

Course content

UNIT I	**10 Hours**
Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.	
UNIT II	**10 Hours**
Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems **ImplantableDrug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump	
UNIT III	**10 Hours**
Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches **Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications **Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers	
UNIT IV	**08 Hours**
Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications	
UNIT V	**07 Hours**
Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts **Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications	

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

VIII SEMESTER
16BPH81: BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and
Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course Outcome

At the end of the course students will be able to...

CO1	Learn the measure of central tendency, dispersion and correlation
CO2	Understand the regression analysis and probability theory
CO3	Learn the parametric and non-parametric tests
CO4	Discuss the designing of methodology for research
CO5	Learn the basic concepts of clinical trial
CO6	Explain the design and analysis of experiments
CO7	Learn different types of graphical representation of data
CO8	Learn the basic concept for research, design of experiments and ethical practices

Course content

UNIT I	**10 Hours**
Introduction: Statistics, Biostatistics, Frequency distribution **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems **Correlation**: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	
UNIT II	**10 Hours**
Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test**: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference	
UNIT III	**10 Hours**
Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases	

UNIT IV	08 Hours
Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials** **Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	
UNIT V	**07 Hours**
Design and Analysis of experiments: **Factorial Design:** Definition, 2^2, 2^3 design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques	

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

16BPH81: SOCIAL AND PREVENTIVE PHARMACY (Theory)

45 Hours

Scope:
The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:
After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Course Outcome

At the end of the course students will be able to...

CO1	Recognize the concepts and evaluation of public health
CO2	Relate food to nutrition health, balanced diet, deficiencies and its prevention
CO3	Illustrate sociocultural factors and its relation with health
CO4	Identify avoidable habits for personal hygiene and health
CO5	Explain the principles on the prevention and control of communicable and non-communicable diseases.
CO6	Identify National health programs its objectives functioning and outcomes
CO7	Recognize the community services in rural, urban and school health
CO8	Explain the general measures and strategies to be followed in social and preventive pharmacy

Course content

UNIT I	**10 Hours**
Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. **Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. **Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health **Hygiene and health:** personal hygiene and health care; avoidable habits	
UNIT II	**10 Hours**
Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse	
UNIT III	**10 Hours**
National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.	
UNIT IV	**08 Hours**
National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	
UNIT V	**07 Hours**
Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school	

Recommended Books (Latest edition)*:*

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited

by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN- 14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

16BPH83: PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

Course Outcome

At the end of the course students will be able to...

CO1	Describe the concept of pharmaceutical marketing.
CO2	Enumerate the concept of product management in pharmaceutical industry
CO3	Discuss the various components of promotion of pharmaceutical products
CO4	Explain the different pharmaceutical marketing channels
CO5	Discuss the role and responsibility of professional sales representative
CO6	Discuss the roles and responsibilities of pricing authorities in India
CO7	Discuss the emerging concepts of marketing
CO8	Discuss the role market research

Course contents

UNIT I	**10 Hours**
Marketing: Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behaviour; industrial buying behaviour. **Pharmaceutical market:** Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research	
UNIT II	**10 Hours**
Product decision: Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	
UNIT III	**10 Hours**
Promotion: Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products	
UNIT IV	**08 Hours**
Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. **Professional sales representative (PSR):** Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR	
UNIT V	**07 Hours**
Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). **Emerging concepts in marketing:** Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, Indian Context, Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

16BPH84ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course Outcome

At the end of the course students will be able to...

CO1	Explain the process of drug discovery , development and generic product development
CO2	Describe the regulatory approval process and registration procedures for API and drug products in various countries
CO3	Learn the basic understanding of regulations of India with other global regulated markets
CO4	Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
CO5	Explain basic understanding of developing clinical trial protocols
CO6	Understand the concept of pharmacovigilance and its significance
CO7	Learn the basicunderstanding the importance of Orange book, Federal Register, Code of Federal Regulatory, and Purple book
CO8	Explain the Registration of Indian drug product in overseas market

Course content

UNIT I	**10 Hours**
New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development	
UNIT II	**10 Hours**
Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. **Regulatory authorities and agencies** Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)	
UNIT III	**10 Hours**
Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.	
UNIT IV	**08 Hours**
Clinical trials Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials	
UNIT V	**07 Hours**
Regulatory Concepts Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical

Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

16BPH85: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI)
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Outcome

At the end of the course students will be able to...

CO1	Discuss the importance of drug safety monitoring and the development of pharmacovigilance program
CO2	Identify adverse drug reactions and manage it
CO3	Explain international standards for classification of diseases and drugs
CO4	Describe about national and international pharmacovigilance program and the terminologies used
CO5	Develop and establish pharmacovigilance program in an organization
CO6	Recognize various methods of drug safety surveillance and communication in pharmacovigilance
CO7	Explain the methods to generate safety data during the phases of clinical trial and recognize the role of ICH and GCP guidelines.
CO8	Explain pharmacogenomics of adverse drug reactions and evaluate drug safety in special population

Course Content

UNIT I	**10 Hours**
Introduction to Pharmacovigilance • History and development of Pharmacovigilance • Importance of safety monitoring of Medicine • WHO international drug monitoring programme • Pharmacovigilance Program of India (PvPI) **Introduction to adverse drug reactions** • Definitions and classification of ADRs • Detection and reporting • Methods in Causality assessment • Severity and seriousness assessment • Predictability and preventability assessment • Management of adverse drug reactions **Basic terminologies used in pharmacovigilance** • Terminologies of adverse medication related events • Regulatory terminologies	

UNIT II	10 Hours
Drug and disease classification • Anatomical, therapeutic and chemical classification of drugs • International classification of diseases • Daily defined doses • International Non proprietary Names for drugs **Drug dictionaries and coding in pharmacovigilance** • WHO adverse reaction terminologies • MedDRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary **Information resources in pharmacovigilance** • Basic drug information resources • Specialised resources for ADRs **Establishing pharmacovigilance programme** • Establishing in a hospital • Establishment & operation of drug safety department in industry • Contract Research Organisations (CROs) • Establishing a national programme	
UNIT III	**10 Hours**
Vaccine safety surveillance • Vaccine Pharmacovigilance • Vaccination failure • Adverse events following immunization **Pharmacovigilance methods** • Passive surveillance – Spontaneous reports and case series • Stimulated reporting • Active surveillance – Sentinel sites, drug event monitoring and registries • Comparative observational studies – Cross sectional study, case control study and cohort study • Targeted clinical investigations **Communication in pharmacovigilance** • Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management • Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	

UNIT IV	08 Hours
Safety data generation • Pre clinical phase • Clinical phase • Post approval phase	
ICH Guidelines for Pharmacovigilance • Organization and objectives of ICH • Expedited reporting • Individual case safety reports • Periodic safety update reports • Post approval expedited reporting • Pharmacovigilance planning • Good clinical practice in pharmacovigilance studies	
UNIT V	**07 Hours**
Pharmacogenomics of adverse drug reactions • Genetics related ADR with example focusing PK parameters. **Drug safety evaluation in special population** • Paediatrics • Pregnancy and lactation • Geriatrics **CIOMS** • CIOMS Working Groups • CIOMS Form **CDSCO (India) and Pharmacovigilance** • D&C Act and Schedule Y • Differences in Indian and global pharmacovigilance requirements	

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton

Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

16BPH86ET: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

45 hours

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. Know WHO guidelines for quality control of herbal drugs
2. Know Quality assurance in herbal drug industry
3. Know the regulatory approval process and their registration in Indian and international markets
4. Appreciate EU and ICH guidelines for quality control of herbal drugs

Course Outcome

At the end of the course students will be able to...

CO1	Explain basic tests for drugs to obtain dossage form for pharmaceutical substances and medicinal plants
CO2	Explain methods for evaluation of pharmaceutical substances, medicinal plants and commercial crude drugs along with WHO guidelines for quality control for herbal drugs
CO3	Describe guidelines for cGMP, GAP, GMP and GLP for quality assurance of herbal drugs in industry
CO4	Describe guidelines for quality control of herbal drugs and evaluation of safety and efficacy of herbal medicines.
CO5	Explain regulatory approval process and their registration in Indian and international markets.
CO6	Explain Drugs and Cosmetic Act Provosion for herbal drug preparation and marketing
CO7	Explain WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.
CO8	Explain role of chemical and biological markers in standardization of herbal products

Course Contents

UNIT I	**10 Hours**
Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use	
UNIT II	**10 Hours**
Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.	
UNIT III	**10 Hours**
EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	
UNIT IV	**08 Hours**
Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions	
UNIT V	**07 Hours**
Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

16BPH87ET: COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Outcome

At the end of the course students will be able to...

CO1	Explain the various stages of drug discovery
CO2	Learn the concept of bioisosterism and drug resistance
CO3	Describe physicochemical Properties and the techniques involved in QSAR
CO4	Learn introduction to Bioinformatics and Cheminformatics
CO5	Learn methods in molecular and quantum mechanics
CO6	Explain various structure based drug design methods (Molecular docking, Denovo drug design)
CO7	Learn the concept of pharmacophore and modelling techniques
CO8	Explain the various techniques in Virtual Screening

Course Content:

UNIT I	**10 Hours**
Introduction to Drug Discovery and Development Stages of drug discovery and development **Lead discovery and Analog Based Drug Design** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. **Analog Based Drug Design:** Bioisosterism, Classification, Bioisosteric replacement. Any three case studies	
UNIT II	**10 Hours**
Quantitative Structure Activity Relationship (QSAR) SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA	
UNIT III	**10 Hours**
Molecular Modeling and virtual screening techniques **Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, **Molecular docking**: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design	
UNIT IV	**08 Hours**
Informatics & Methods in drug design Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases	
UNIT V	**07 Hours**
Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination	

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic

Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

16BPH88ET: CELL AND MOLECULAR BIOLOGY (Theory)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi- cellular organisms such as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course Outcome

At the end of the course students will be able to...

CO1	Describe the history of cell and molecular biology
CO2	Describe cellular functioning and composition
CO3	Describe the chemical foundations of cell biology and its applications.
CO4	Explain the DNA properties of cell biology, protein engineering and applications
CO5	Describe protein structure and function and its applications and Regularities in Protein Pathways
CO6	Describe cellular membrane structure and function
CO7	Describe basic molecular genetics mechanisms, science of genetics and explain transgenic animal models.
CO8	Describe Cell Cycle

Course content

UNIT I	**10 Hours**
a) Cell and Molecular Biology: Definitions theory and basics and Applications. b) Cell and Molecular Biology: History and Summation. c) Theory of the Cell? Properties of cells and cell membrane. d) Prokaryotic versus Eukaryotic e) Cellular Reproduction f) Chemical Foundations – an Introduction and Reactions (Types)	
UNIT II	**10 Hours**
a) DNA and the Flow of Molecular information b) DNA Functioning c) DNA and RNA d) Types of RNA e) Transcription and Translation	
UNIT III	**10 Hours**
a) Proteins: Defined and Amino Acids b) Protein Structure c) Regularities in Protein Pathways d) Cellular Processes e) Positive Control and significance of Protein Synthesis	
UNIT IV	**08 Hours**
a) Science of Genetics b) Transgenics and Genomic Analysis c) Cell Cycle analysis d) Mitosis and Meiosis e) Cellular Activities and Checkpoints	
UNIT V	**07 Hours**
a) Cell Signals: Introduction b) Receptors for Cell Signals c) Signaling Pathways: Overview d) Misregulation of Signaling Pathways e) Protein-Kinases: Functioning	

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers &

Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C. RA Goldshy et. al., : Kuby Immunology

16BPH89ET: COSMETIC SCIENCE (Theory)

45 Hours

Scope:

Cosmetic sciences is an upcoming discipline that includes formulation, manufacture and evaluation of various cosmetics including cosmeceuticals. It requires knowledge of fundamentals of skin care, hair care, cosmetic problems associated with hair and scalp and the use of herbs in cosmetics.

Objectives: Upon completion of the subject the student shall be able to

- Basic structure of skin, hair and problems associated with teeth and gums
- Understand the formulation of various skin care products including facial creams, deodorants and antiperspirants
- Will know the basics of the formulation of shampoos, hair conditioners, hair oils and dentifrices
- Will be aware of the fundamentals of sun protection and the formulation of sunscreens
- Understand the principles behind cosmetic evaluation using various instruments such as sebumeter and corneometer
- Will understand the common cosmetic problems associated with skin, hair and scalp

Course Outcome

At the end of the course students will be able to...

CO1	Classify and define Cosmetics and Cosmeceuticals as per Indian and EU regulations
CO2	Describe the role of cosmetic excipients and building blocks in the formulation of cosmetics
CO3	Explain the structure and function of the skin, hair, teeth and gums
CO4	Describe the fundamentals of sun protection and the formulation of Sunscreens, antiperspirants and deodorants
CO5	Formulate cosmetics for skin care and hair care as well as dental and oral care
CO6	Design herbal cosmetics for skin care, hair care and oral care
CO7	Evaluate cosmetics for various physico-chemical properties.

CO8	Design cosmetics and cosmeceuticals that address the problems of dry skin, acne, dermatitis, prickly heat, wrinkles, blemishes, hair fall, Dandruff, body odour, bleeding gums, mouth odour, teeth discoloration and sensitive teeth.

Course Contents

UNIT I	**10 Hours**
Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs **Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application **Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle. **Oral Cavity:** Common problem associated with teeth and gums**.**	
UNIT II	**10 Hours**
Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmecuticals. **Antiperspirants & deodorants**- Actives & mechanism of action. **Principles of formulation and building blocks of Hair care products:** Conditioning shampoo, Hair conditioner,anti-dandruff shampoo, Hair oils. Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.	
UNIT III	**10 Hours**
Sun protection, Classification of Sunscreens and SPF. **Role of herbs in cosmetics:** Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove **Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-cream and toothpaste	

UNIT IV	**08 Hours**
Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits	
UNIT V	**07 Hours**
Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action	

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

16BPH90ET: PHARMACOLOGICAL SCREENING METHODS (Theory)

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Course Outcome

At the end of the course students will be able to...

CO1	Describe the applications of common laboratory animals, explain CPCSEA and OECD guidelines governing the for maintenance, breeding and conduct of experiments on laboratory animals. Explain blood withdrawal techniques and drug administration in animals.
CO2	Explain dose, dose calculations grouping of animals, species selection, sex in conducting the animal experimentation.
CO3	Describe the research Study of screening animal models for Diuretics, no-tropics, anti-Parkinson's, anti asthmatics.
CO4	Explain screening methods of CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti parkinsonism, alzheimer's disease
CO5	Explain screening methods of for CVS activity- anti hypertensives, diuretics, anti arrhythmic, anti dyslepidemic,
CO6	Explain screening methods of for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants
CO7	Explain screening methods of antiulcer, antidiabetic, anticancer and antiasthmatics
CO8	Explain screening methods of Research methodology and Bio-statistics

Course Contents

UNIT I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia	
UNIT II	**10 Hours**
Preclinical screening models **a) Introduction:** Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. **b) Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's, anti asthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	
UNIT III	**10 Hours**
Preclinical screening models: for ANS activity, sympathomimetics sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	
UNIT IV	**10 Hours**
Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants, Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics	
UNIT V	**07 Hours**
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design, Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K. Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

16BPH91ET: ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

Course Outcome

At the end of the course students will be able to...

CO1	Explain theoretical principles of, MASS and NMR spectroscopy.
CO2	Learn basic instrumentation of NMR and mass spectrometer.
CO3	Explain theoretical principles of x-rays, instrumentation and identification of organic compounds.
CO4	Learn basic principles and instrumentation of thermal analysis
CO5	Describe general principles and procedures involved in extraction techniques.
CO6	Learn basic instrumentation and applications of hyphenated techniques.
CO7	Explain general principles and instrumentation of radioimmuno assay
CO8	Learn basic knowledge about the calibration of analytical instruments.

Course Content

UNIT I	**10 Hours**
Nuclear Magnetic Resonance spectroscopy Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications	
UNIT II	**10 Hours**
Thermal Methods of Analysis: Principles, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications	
UNIT III	**10 Hours**
Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer Fluorimeter, Flame Photometer, HPLC and GC	
UNIT IV	**08 Hours**
Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay **Extraction techniques**: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction	
UNIT V	**07 Hours**
Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS	

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar

7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi Spectrophotometric identification of Organic Compounds by Silverstein.

16BPH92ET: DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)

45 Hours

Scope:

This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.
- Appreciate the regulatory and commercial aspects of dietary supplements including health claims

Course Outcome

At the end of the course students will be able to...

CO1	Explain the definition, classification of nutraceuticals, functional foods and dietary supplements and role of nutraceuticals in prevention or cure various diseases.
CO2	Explain about effect of nutrition to maintain healthy life of public included maternal and child health and effects of education about nutrition in community.
CO3	Describe about source, chemistry and uses of several natural nutraceuticals.
CO4	Describe occurrence, chemical nature and medicinal benefits of natural nutraceuticals belong to different phytochemical categories.
CO5	Explain about different free radical which generate in body and their effects and different dietary fibres and complex carbohydrate as functional food ingredients.

CO6	Explain the role of free radicals in development of different diseases and aging
CO7	Explain the role of natural and synthetic antioxidants, functional foods in prevention of chronic diseases.
CO8	Explain effects of processing, storage, environmental factors and regulatory aspects for maintaining quality of nutraceuticals.

Course Content

UNIT I	**07 Hours**
a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals /functional foods: Spirulina Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds	
UNIT II	**15 Hours**
Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following a. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin b. Sulfides: Diallyl sulfides, Allyl trisulfide. c. Polyphenolics: Reservetrol d. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f. Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g. Tocopherols h. Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like	
UNIT III	**07Hours**
a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. b. Dietary fibres and complex carbohydrates as functional food ingredients.	

UNIT IV	10 Hours
a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing. b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. c. Functional foods for chronic disease prevention	
UNIT V	**06 Hours**
a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn.,Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

16BPH93ET: Pharmaceutical Product Development (Theory)

45 Hours

Scope:

This subject deals with the process of pharmaceutical process development with emphasis on the excipients used, optimisation techniques and quality control testing. A brief study of the regulatory considerations in product development is also included in the scope of study.

Objectives:

- Study of pharmaceutical excipients and their specific industrial applications
- Study of the optimisation techniques of product development with specific examples
- Quality control of packaging material
- To understand the regulatory considerations of product development

Course Outcome

At the end of the course students will be able to...

CO1	Explain the various regulations related to preformulation, formulation development
CO2	Learn quality control testing for different types of dosage forms
CO3	Explain various Pharmaceutical excipients in pharmaceutical product development such as Solvents and solubilizers, Suspending and emulsifying agents
CO4	Explain cyclodextrins & Non - ionic surfactants and their applications
CO5	Learn selection and application of excipients in pharmaceutical formulations
CO6	Explain optimization by factorial designs and their applications.
CO7	Learn the application of QbDin pharmaceutical product development.
CO8	Explain regulatory considerations of packaging materials for pharmaceutical product development-

Course Content

UNIT I	**10 Hours**
Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms	
UNIT II	**10 Hours**
An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Solvents and solubilizers ii. Cyclodextrins and their applications iii. Non - ionic surfactants and their applications iv. Polyethylene glycols and sorbitols v. Suspending and emulsifying agents vi. Semi solid excipients	
UNIT III	**10 Hours**
An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Tablet and capsule excipients ii. Directly compressible vehicles iii. Coat materials iv. Excipients in parenteral and aerosols products v. Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications	
UNIT IV	**08 Hours**
Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development	
UNIT V	**07 Hours**
Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.	

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick,

Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.Advanced Review Articles related to the topics