

CRITERIA – I

CURRICULAR ASPECTS

Key Indicator-1.3	Curriculum Enrichment
Metric - 1.3.1 (Q ₁ M)	Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum

Viswambhara Educational Society

VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES

Affiliated to Kakatiya University, Approved by PCI-New Delhi, AICTE, New Delhi P.O. BOLLIKUNTA, WARANGAL- 506 005 (Telangana State)





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Affiliated to Kakatiya University, Approved by PCI-New Delhi, AICTE, New Delhi P.O. BOLLIKUNTA, WARANGAL- 506 005 (Telangana State)

1.3.1: Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum

S. No.	Subject Name	Subject Code	(Year or Semester) Course
1	Community Pharmacy	2.5	II/ PHARM. D
2	Pharmaceutical Jurisprudence	3.4	III/ PHARM. D
3.	Hospital Pharmacy	4.2	IV/ PHARM. D
4.	Clinical Pharmacy	4.3	IV/ PHARM. D
5.	Clinical Research	5.1	V/ PHARM. D
6.	Communication skills	BP 105 T & BP 111P	I/ B PHARM
7.	Environmental Sciences	BP 206 T	II/ B PHARM
8.	Pharmaceutical Jurisprudence	BP 505 T	V/ B PHARM
9.	Pharmacy Practice	BP 703 T	VII/ B PHARM
10.	Social and Preventive Pharmacy	BP 802 T	VIII/ B PHARM
11	Pharmaceutical Regulatory Science	BP804ET	VIII/ B PHARM

*Note:

B. Pharmacy:

Semester wise

Pharm.D

Year wise



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साप्ताहिक/WEEKLY

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No. 19

NEW DELHI, SATURDAY, MAY 10-MAY 16, 2008 (VAISAKHA 20, 1930)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके। (Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4 [PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सिम्मिलित हैं। [Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ: बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08-- भारतीय रिजर्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा कार्यपालक निदेशक

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[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare (Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

- Short title and commencement. (1) These regulations may be called the Pharm.D. Regulations 2008.
 - (2) They shall come into force from the date of their publication in the official Gazette.
- Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

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CHAPTER-II

- 3. Duration of the course.
 - a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases
 - Phase I consisting of First, Second, Third, Fourth and Fifth academic year.
 - Phase II consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.
 - b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases
 - Phase I consisting of First and Second academic year.
 - Phase II consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.
- 4. Minimum qualification for admission to. -
- a) Pharm.D. Part-I Course A pass in any of the following examinations -
- (1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

- (2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
- (3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.



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A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

- Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
 - i) Pharm.D. Programme 30 students.
 - ii) Pharm.D. (Post Baccalaureate) Programme 10 students.
- 6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.
- 7. Course of study. The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

TABLES

First Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

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Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	17	9	6 = 32

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	1	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	16	15	5 = 36

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Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	15	12	6 = 33

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	2	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4 = 32

^{*} Attending ward rounds on daily basis.



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Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments
- 8. Syllabus. The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.
- Approval of the authority conducting the course of study. (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.
 - (2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.
 - (3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

- 10. Examination. (1) Every year there shall be an examination to examine the students.
 - (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
 - (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below:

TABLES

First Year examination:

S.No.	Name of Subject	Maximu	Maximum marks for Theory			n marks for P	racticals
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70‡	30*	100*
				600			600 = 1200

* for Biology.

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Second Year examination:

S.No.	Name of Subject	Maximu	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total	
2.1	Pathophysiology	70	30	100	-			
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100	
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100	
2.4	Pharmacology-I	70	30	100	-	-	-	
2.5	Community Pharmacy	70	30	100	*	2		
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100	
				600			300 = 900	

Third Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	2
				600			400 = 1000



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Fifth Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100			2
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

- * Attending ward rounds on daily basis.
- ** 30 marks viva-voce (oral)

70 marks - Thesis work

- 11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.
- Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
 - (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
 - (3) Practical examination shall also consist of a viva –voce (Oral) examination.
 - (4) Clerkship examination Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.
- 13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.
 - (2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.
 - (3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination

(20 marks);

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc.

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(10 marks).

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- 14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.
- 15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.
- 16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
 - (2) Every student has to undergo one year internship as per Appendix-C to these regulations.
- 17. Approval of examinations.— Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix-D to these regulations.
- 18. Certificate of passing examination. Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

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CHAPTER-III Practical training

- 19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
- 20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
 - (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions
- 21. Objectives of project work.— The main objectives of the project work is to—
 - (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretation skills.
- 22. Methodology.— To complete the project work following methodology shall be adopted, namely:—
 - (i) students shall work in groups of not less than two and not more than four under an authorised teacher:
 - (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
 - (iii)project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
 - (iv)project work shall be approved by the institutional ethics committee;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi)two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

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- 23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
 - (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
 - (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.
- 24. Evaluation.— The following methodology shall be adopted for evaluating the project work—
 - (i) Project work shall be evaluated by internal and external examiners.
 - (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
 - (iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)
(v) Final evaluation of project work shall be done on the following items:	Marks
(v) Final evaluation of project work shall be done on the following items:a) Write up of the seminar	Marks (17.5)
a) Write up of the seminar	(17.5)
a) Write up of the seminar b) Presentation of work	(17.5) (17.5)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

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2.5 COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

- 1. Scope: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
- 2. Objectives: Upon completion of the course, the student shall be able to
 - a. know pharmaceutical care services;
 - know the business and professional practice management skills in community pharmacies;
 - do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

- Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
- Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1.	Synopsis	10	
2.	Major Experiment	30	
	(Counselling of patients with specific diseases emphasis should	be given of	on
	Counselling introduction, content, process and conclusion)	-	
3.	Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15	
4.	Prescription Analysis (Analyzing the prescriptions for probable drug in	iteraction ar	nd
	ability to tell the management)	15	
5	Viva – Voce	10	



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4. Lecture wise programme:

Topics

1 Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist

2 Community Pharmacy Management

- a) Selection of site, Space layout, and design
- b) Staff, Materials- coding, stocking
- c) Legal requirements
- d) Maintenance of various registers
- e) Use of Computers: Business and health care soft wares
- 3 Prescriptions parts of prescription, legality & identification of medication related problems like drug interactions.

4 Inventory control in community pharmacy

Definition, various methods of Inventory Control

ABC, VED, EOQ, Lead time, safety stock

5 Pharmaceutical care

Definition and Principles of Pharmaceutical care.

6 Patient counselling

Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels

7 Patient medication adherence

Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 Health screening services

Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 OTC Medication- Definition, OTC medication list & Counselling

10 Health Education

WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

Commonly occurring Communicable Diseases, causative agents,

Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,

Syphilis, Gonorrhea and AIDS

Balance diet, and treatment & prevention of deficiency disorders

Family planning – role of pharmacist

11 Responding to symptoms of minor ailments

Relevant pathophysiology, common drug therapy to,

Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 Essential Drugs concept and Rational Drug Therapy

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Role of community pharmacist

13 Code of ethics for community pharmacists

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3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

- Scope of the Subject: (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
- 2. Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, and appreciate)
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal, B.M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

- Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

- Pharmaceutical Legislations A brief review.
- Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
- Drugs and Cosmetics Act, 1940, and its rules 1945.

Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.

Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.

Constitution and Functions of DTAB, DCC, CDL.

Qualification and duties Govt. analyst and Drugs Inspector.

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4. Pharmacy Act -1948.

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

- 5. Medicinal and Toilet Preparation Act -1955.
 - Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
- 7. Study of Salient Features of Drugs and magic remedies Act and its rules.
- 8. Study of essential Commodities Act Relevant to drugs price control Order.
- 9. Drug Price control Order & National Drug Policy (Current).
- 10. Prevention Of Cruelty to animals Act-1960.
- 11. Patents & design Act-1970.
- 12. Brief study of prescription and Non-prescription Products.

4. Assignments:

Format of the assignment

- 1. Minimum & Maximum number of pages
- It shall be a computer draft copy
- 3. Reference(s) shall be included at the end.
- 4. Name and signature of the student
- 5. Assignment can be a combined presentation at the end of the academic year.
- 6. Time allocated for presentation may be 8+2 Min

Case studies relating to

- Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
- 2. Various prescription and non-prescription products.
- 3. Medical and surgical accessories.
- 4. Diagnostic aids and appliances available in the market.

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4.2 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

- 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 dispensing, manufacturing of parenteral preparations, drug information, patient
 counselling, and therapeutic drug monitoring for improved patient care.
- 2. Objectives: Upon completion of the course, the student shall be able to
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part -B; Pharmacy Practice section.
- Handbook of pharmacy health care. Edt. Robin J Harman. The Pharmaceutical press.
- 3. Lecture wise programme:

Topics

- 1 Hospital its Organisation and functions
- 2 Hospital pharmacy-Organisation and management
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 The Budget Preparation and implementation
- 4 Hospital drug policy
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication Newsletter

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5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control

Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

- 8 Radio Pharmaceuticals Handling and packaging
- 9 Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

- 1. Assessment of drug interactions in the given prescriptions
- 2. Manufacture of parenteral formulations, powders.
- 3. Drug information queries.
- 4. Inventory control

List of Assignments:

- 1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
- 2. Pharmacy and Therapeutics committee Organization, functions, and limitations.
- 3. Development of a hospital formulary for 300 bedded teaching hospital
- Preparation of ABC analysis of drugs sold in one month from the pharmacy.
- 5. Different phases of clinical trials with elements to be evaluated.
- Various sources of drug information and systematic approach to provide unbiased drug information.
- Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

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4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject:

Upon completion of the subject student shall be able to (Know, do, appreciate) -

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions The Society of Hospital Pharmacists of Australia.
- Basic skills in interpreting laboratory data Scott LT, American Society of Health System Pharmacists Inc.
- Biopharmaceutics and Applied Pharmacokinetics Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

- Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics Rowland and Tozer, Williams and Wilkins Publication.
- Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

- 1. Definitions, development and scope of clinical pharmacy
- 2. Introduction to daily activities of a clinical pharmacist
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

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3. Patient data analysis

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

- 4. Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests

5. Drug & Poison information

- a. Introduction to drug information resources available
- b. Systematic approach in answering DI queries
- c. Critical evaluation of drug information and literature
- d. Preparation of written and verbal reports
- e. Establishing a Drug Information Centre
- f. Poisons information- organization & information resources

6. Pharmacovigilance

- a. Scope, definition and aims of pharmacovigilance
- b. Adverse drug reactions Classification, mechanism, predisposing factors, causality assessment [different scales used]
- c. Reporting, evaluation, monitoring, preventing & management of ADRs
- d. Role of pharmacist in management of ADR.
- Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
- 8. Pharmaceutical care concepts
- 9. Critical evaluation of biomedical literature
- 10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

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Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

- 1. Pharmacological
- 2. Toxicological
- 3. IND Application
- Drug characterization
- 5. Dosage form

2. Clinical development of drug:

- 1. Introduction to Clinical trials
- 2. Various phases of clinical trial.
- 3. Methods of post marketing surveillance
- 4. Abbreviated New Drug Application submission.
- Good Clinical Practice ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
- 6. Challenges in the implementation of guidelines
- 7. Ethical guidelines in Clinical Research
- 8. Composition, responsibilities, procedures of IRB / IEC
- 9. Overview of regulatory environment in USA, Europe and India.
- 10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
- 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
- 12. Informed consent Process
- 13. Data management and its components
- 14. Safety monitoring in clinical trials.



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APPENDIX-B

(See regulation 9) CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

- Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

- 1. Institution with their own hospital of minimum 300 beds.
- 2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
- 3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
- 4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

- a) Tertiary care hospitals are desirable
- b) Medicine[compulsory], and any three specialization of the following
 - 1. Surgery
 - 2. Pediatrics
 - 3. Gynecology and obstetrics

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- 4. Psychiatry
- 5. Skin and VD
- 6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES BOLLIKUNTA, WARANGAL – 506 005 Time Table for Pharm.D II Year

	2022-2023
Cal	YEAR:
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	TABLE FOR
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	TIME

01.45рш-4.30рш	Pharmaceutical Microbiology	Community Pharmacy (Tutorial)	Case Presentation	Pharmaceutical Microbiology (Tutorial)	Pharmacognosy and Phytochemistry	Pharmacotherapeutics - I
01.10pm- 01.45pm		L	n	z C	, =	
12.20pm-01.10pm	Community	Library	Pharmacotherapeuti cs - I	Pathophysiology	Community	
11.30ат-12.20рт	Pharmacognosy & Phytochemistry	Pharmaceutical Microbiology	Pharmacology - I	Pharmaceutical Microbiology	Pathophysiology	Hospital Posting
10.40am-11.30am	Pathophysiology	Pharmacology I	Pharmacognosy & Phytochemistry	Pharmacotherapeuti cs - I (Tutorial)	Pharmacology – I (Tutorial)	
9.50am-10.40am	Pharmacotherapeuti cs-1	Pharmacognosy and Phytochemistry	Pathophysiology	Pharmacology I	Pharmaceutical Microbiology	Pharmacotherap eutics – I
DAY	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Pathophysiology

Pharmaceutical Microbiology

Pharmacognosy and Phytochemistry

Pharmacology - I

Community Pharmacy

Pharmacotherapeutics - 1

: Mr. V. Mouna Reddy : Mrs.Ch. Kishore

Dr. V. Padmaja

Mr. J. Karunakar

Ms. P. Nagasowmya

Mrs. G.Sruthi

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TIME - TABLE FOR THE ACADAMIC YEAR: 2022-2023 Time Table for Pharm.D III Year

01.45pm-4.30pm	Pharmaceutical Analysis	Pharmacology – II	Medicinal Chemistry	Hospital Posting	Hospital Posting / Pharmacotherapeutics - II	Pharmaceutical Formulations
01.10pm- 01.45pm		J 5	z	· =	Hos	
12.20рт-01.10рт	Pharmacology –	Pharmacology – II	Pharmacology – II (Tutorial)	Posting	Posting	Pharmaceutical Jurisprudence
11.30am-12.20pm 12.20pm-01.10pm	Pharmaceutical Formulations	Pharmaceutical Analysis	Pharmaceutical Analysis	Hospital Posting	Hospital Posting	Medicinal Chemistry
10.40am-11.30am	Medicinal Chemistry	Medicinal Chemistry (Tutorial)	Pharmaceutical Jurisprudence	Pharmacotherap eutics – II	Pharmacotherap eutics – II	Pharmaceutical Formulations (Tutorial)
9.50am-10.40am	Pharmaceutical Analysis	Pharmaceutical Formulations	Medicinal Chemistry	Pharmaceutical Analysis (Tutorial)	Pharmacotherap eutics - II	Pharmacology –
DAY	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Pharmacology - II

Mrs. P.Priyanka Mr. G. Sumanth Mrs. K.Manasa Pharmaceutical Analysis

Pharmaceutical Jurisprudence Pharmacotherapeutics - II

Medicinal Chemistry

Pharmaceutical Formulations

Dr. K. Rathnakar Reddy Mr. M. Sandyarani Mrs. D.Jtothi

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES BOLLIKUNTA, WARANGAL - 506 005 Time Table for Pharm.D IV Year

TIME TABLE FOR THE ACADEMIC YEAR: 2022-2023

	9.50am-10.40am	10.40am- 11.30am	11.30am- 12.20pm	12.20pm- 01.10pm	01.10pm- 01.45pm		01.45pm-4.30pm	
	Hospital Posting/	Hospital Posting/ Clinical rotations	Clinical	Clinical Pharmacy		Case d	Case discussion/ Documentation	ntation
1		Hospital Posting/ Clinical rotations	Clinical rotations		1	Clinical	Pharmacothera	Hospital
Wednesday	Pharmacotherapeutics - III (Tutorial)	tics - III (Tutorial)	Hospital Posting/	Hospital Posting/ Clinical rotations	n		Hospital Pharmacy (Lab)	ab)
	Biostatistics & Research Methodology	Biopharmaceutic s & Pharmacokinetic s	Library	Clinical Toxicology	z o	Biopharm	Biopharmaceutics & Pharmacokinetics	cokinetics
	Clinical Toxicology	Pharmacotherape utics – III	Biopharmaceutic s & Pharmacokinetic s	Hospital Pharmacy	Ξ	Pharmacothera peutics – III	Biostatistics & Research Methodology	Hospital
	Biopharmaceutics & Pharmacokinetics	Clinical Pharmacy	harmacy	Biostatistics & Research Methodology		3	Clinical Pharmacy (Lab)	(qı

Pharmacotherapeutics - III Hospital Pharmacy

Clinical Pharmacy

Biostatistics & Research Methodology

Biopharmaceutics & Pharmacokinetics Clinical Toxicology

V.Mounareddy Dr.K. Naresh G. Sriranjini

Dr. T Prathyusha Rani

Mrs. M. Sandhya Rani

Mr. M. Tejaswi

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Time Table for Pharm.D V Year

TIME - TABLE FOR THE ACADEMIC YEAR: 2022-2023

0pm	entations	ab	ntations	ting	qı	ting
01.45pm-4.30pm	Monograph Presentations	Journal Club	Monograph Presentations	Hospital Posting	Journal Club	Hospital Posting
01.10pm- 01.45pm		_	n	z))	н
12.20pm-01.10pm	PEPE	Clinical Research	PEPE			
11.30am- 12.20pm	Project Work	TDM	TDM	Hospital / Project Work Hospital / Project Work	/ Project Work	Hospital / Project Work
10.40am- 11.30am	CPK and TDM / Project Work	CPK and TDM	CPK and TDM	Hospital	Hospita	Hospital
9.50am- 10.40am	Clinical	PEPE	Clinical			
DAY	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Clinical Research

Dr. B. Sharath babu

Mr. M. Vijay Reddy

Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Pharmacoepidemiology and Pharmacoeconomics

Prof. Y. Madhusudan Rao

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Pharmacy Council of India New Delhi

Rules & Syllabus for the Bachelor of Pharmacy (B. Pharm) Course

[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B. Pharm) course regulations 2014]



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CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS)of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall 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.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

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7. 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.

7.1. Credit assignment

7.1.1. 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.

7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover 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 attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

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9. 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	Tuto rial	Credit points
BP101T	Human Anatomy and Physiology I— Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills - Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills - Practical*	2	-	1
BP112RBP	Remedial Biology - Practical*	2	-	1
	Total	32/34 ^{\$} /36 [#]	4	27/29 ^{\$} /30

^{*}Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.



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^SApplicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

^{*} Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit
BP201T	Human Anatomy and Physiology II - Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry - Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy - Theory *	3		3
BP206T	Environmental sciences - Theory *	3	ii ii	3
BP207P	Human Anatomy and Physiology II -Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I- Practical	4	-	2
BP209P	Biochemistry - Practical	4	-	2
BP210P	Computer Applications in Pharmacy - Practical*	2	-	1
	Total	32	4	29

^{*}Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II - Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology - Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II - Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology - Practical	4	-	2
BP 308P	Pharmaceutical Engineering -Practical	4	-	2
	Total	28	4	24



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Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III- Theory	. 3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I- Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and 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
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI- Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II- Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence - Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	2	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	27	5	26



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Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III - Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology - Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III - Practical	4	-	2
BP608P	Pharmacology III - Practical	4	-	2
BP609P	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
BP701T	Instrumental Methods of Analysis - Theory	3	1	4
BP702T	Industrial PharmacyII - Theory	3	1	4
BP703T	Pharmacy Practice - Theory	3	1	4
BP704T	Novel Drug Delivery System - Theory	3	1	4
BP705P	Instrumental Methods of Analysis - Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	28	5	24

^{*} Non University Examination (NUE)



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Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3+3=6	1+1=2	4+4=
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
	Total	24	4	22

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27/29 ^{\$} /30 [#]
II	29
Ш	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	209/211 ^{\$} /212 [#]

^{*} The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

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⁸Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

[&]quot;Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

10. Program Committee

- The B. Pharm. program shall have a Program Committee constituted by the Head
 of the institution in consultation with all the Heads of the departments.
- 2. The composition of the Program 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 program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

- i. Periodically reviewing the progress of the classes.
- 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 Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table -X.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted 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.



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Tables-X: Schemes for internal assessments and end semester examinations semester wise

•	emester I	
TOT COURS		The second secon
THE CT HAT		
assessment		The second secon
s and		

Course			Internal Assessment	ssessment		End Semester Exams	ter Exams	Total
code	Name of the course	Continuous	Sessional Exams	Exams	Total	Media	;	Marks
		Mode	Marks	Duration	10121	Marks	Duration	SA INTA
BP101T	Human Anatomy and Physiology I- Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	2	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I - Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BPIIIP	Communication skills Practical*	S	S	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	70/75 ⁵ /80#	115/125 ⁵ /130#	23/24 ⁵ /26" Hrs	185/2005/210#	490/525 ⁸ / 540*	31.5/33 ⁸ / 35# Hrs	675/725 ⁸ /

Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

⁵Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoolegyat HSC and appearing for Remedial Mathematics (RM) course.

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* Non University Examination (NUE)

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Semester II

Course			Internal Assessment	sessment		End Seme	End Semester Exams	F
code	Name of the course	Continuous	Session	Sessional Exams	Total		;	Moult
		Mode	Marks	Duration	10121	Marks	Duration	Marks
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences - Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry - Practical	S	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	S	s	2 Hrs	10	15	2 Hrs	25
	Total	80	125	20 Hrs	205	520	30 Hrs	725

The state of the s * The subject experts at college level shall conduct examinations

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Semester III

Course			Internal Assessment	sessment		End Seme	End Semester Exams	
code	Name of the course	Continuous	Session	Sessional Exams	1	Mari		I otal
		Mode	Marks	Duration	I Otal	Marks	Duration	Marks
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI -Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	S	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	S	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	\$	10	4 Hr	15	35	4 Hrs	50
	Total	09	100	20	160	440	28Hrs	009



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Semester IV

Course			Internal Assessment	sessment		End Seme	End Semester Exams	1.4.1
code	Name of the course	Continuous	Session	Sessional Exams	Total	Manha		Morks
2000		Mode	Marks	Duration	I otal	Marks	Duration	Mains
BP401T	Pharmaceutical Organic Chemistry III- Theory	10	15	1 Hr	25	75	3 Hrs	100
P402T	BP402T Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
P404T	BP404T Pharmacology I - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I - Theory	10	15	1 Hr	25	75	3 Hrs	100
P406P	BP406P Medicinal Chemistry I - Practical	S	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	S	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I - Practical	5	10	4 Hrs	15	35	4 Hrs	90
P409P	BP409P Pharmacognosy I - Practical	5	10	4 Hrs	15	35	4 Hrs	50
	Total	70	115	21 Hrs	185	515	31 Hrs	700



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Semester V

Course			Internal Assessment	ssessment		End Seme	End Semester Exams	E
code	Name of the course	Continuous	Session	Sessional Exams	Total			Mault
		Mode	Marks	Duration	I OTAI	Marks	Duration	Marks
BP501T	Medicinal Chemistry II - Theory	10	15	1 Hr	25	75	3 Hrs	100
P502T	BP502T Industrial Pharmacyl- Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial Pharmacyl- Practical	S	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II - Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II - Practical	5	10	4 Hr	15	35	4 Hrs	50
	Total	99	105	17 Hr	170	480	27 Hrs	029



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Semester VI

Course			Internal Assessment	sessment		End Seme	End Semester Exams	F
code	Name of the course	Continuous	Session	Sessional Exams	T. F.	Media		Moule
-		Mode	Marks	Duration	1 0121	Marks	Duration	Marks
BP601T	Medicinal Chemistry III - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology— Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance- Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	S	10	4 Hrs	15	35	4 Hrs	90
BP608P	Pharmacology III - Practical	5	10	4 Hrs	15	35	4 Hrs	50
ВР609Р	Herbal Drug Technology – Practical	s.	10	4 Hrs	15	35	4 Hrs	50
	Total	75	120	18 Hrs	195	555	30 Hrs	750



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Semester VII

Course	Nomo of the county		Internal Assessment	sessment		End S Ex	End Semester Exams	Total
code	Manie of the course	Continuous	Session	Sessional Exams	Total		;	Marks
		Mode	Marks	Duration	1 0121	Marks	Duranon	
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis - Practical	5	10	4 Hrs	15	35	4 Hrs	50
206 PS	BP706 PS Practice School*	25			25	125	5 Hrs	150
	Total	70	20	8Hrs	140	460	21 Hrs	009

* The subject experts at college level shall conduct examinations



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Semester VIII

Course			Internal Assessment	sessment		End Seme	End Semester Exams	=
Course	Name of the course	Continuous	Session	Sessional Exams			:	Morla
cour		Mode	Marks	Duration	TOTAL	Marks	Duration	INTELL
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy - Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory							
BP804ET	Pharmaceutical Regulatory Science - Theory							
BP805ET	Pharmacovigilance - Theory							
	Quality Control and							
BP806E1	Standardization of Herbals – Theory	10 + 10	15 + 15 =	1+1=	25 + 25 =	75 + 75	3 + 3 = 6	100 +
BP807ET	Computer Aided Drug Design – Theory	= 20	30	2 Hrs	50	= 150	HIS	100 = 200
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	,	,			150	4 Hrs	150

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Total

40

60

4 Hrs

100

450

16 Hrs

550

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11.2. Internal assessment: Continuous mode

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		imum arks
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		1.5
Total		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
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / 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 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

I. Multiple Choice Questions (MCQs)	=	$10 \times 1 = 10$
OR		OR
Objective Type Questions (5 x 2)	=	$05 \times 2 = 10$
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	$1 \times 10 = 10$
II. Short Answers (Answer 2 out of 3)	=	$2 \times 5 = 10$

Total = 30 marks

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For subjects having Non University Examination

	Total =	30 marks
II. Short Answers (Answer 4 out of 6)	=	$4 \times 5 = 20$
I. Long Answers (Answer 1 out of 2)	=	$1 \times 10 = 10$

Question paper pattern for practical sessional examinations

I. Synopsis		=	10
II. Experiments		=	25
III. Viva voce		=	05
	Tot	al =	40 marks

12. Promotion and award of grades

A student shall be declared PASSand eligible for getting gradein a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a studentfails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

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Table-XIII:	Tentative	schedule o	fend	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

Question paper pattern for end semester theory examinations

For 75 marks paper

- I. Multiple Choice Questions(MCQs) = $20 \times 1 = 20$ OR Objective Type Questions (10×2) = $10 \times 2 = 20$ (Answer all the questions)
- II. Long Answers (Answer 2 out of 3) = $2 \times 10 = 20$ III. Short Answers (Answer 7 out of 9) = $7 \times 5 = 35$

Total = 75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3) $= 2 \times 10 = 20$ II. Short Answers (Answer 6 out of 8) $= 6 \times 5 = 30$

Total = 50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2) = $1 \times 10 = 10$ II. Short Answers (Answer 5 out of 7) = $5 \times 5 = 25$

Total = 35 marks

Question paper pattern for end semester practical examinations

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

Total = 35 marks



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16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.



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17. Grading of performances

17.1. 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 – XII.

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

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 - 100	0	10	Outstanding
80.00 - 89.99	A	9	Excellent
70.00 - 79.99	В	8	Good
60.00 - 69.99	C	7	Fair
50.00 - 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

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

18. The 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 all the courses by the student during the semester. 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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

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 ABSgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

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$$C_1G_1 + C_2G_2 + C_3G_3 + C_4* ZERO + C_5G_5$$

 $SGPA = C_1 + C_2 + C_3 + C_4 + C_5$

19. 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 statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby 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:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

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

20. Declaration of class

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

21. Project work

All the students shall undertake a projectunder 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.

Pharmaceurical Sciences Scienc

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Evaluation of Dissertation Book:

15 Marks
20 Marks
20 Marks
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.

22. Industrial training (Desirable)

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.

23. 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 leveland grade point shall be awarded.

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24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

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

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. 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.

Applied Pharmaceurical Sciences

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BP105T.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

- 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

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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 Dont's of group discussion

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BP111P.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 Dont's

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

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BP 206 T. 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 10hours

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 10hours

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 10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

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BP 505 T. 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:

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- 2. Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- 4. The code of 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; constitution and functions, Registration of Pharmacists, Offences and

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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)

UNIT-V 07 Hours

- Pharmaceutical Legislations A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

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BP 703T. 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
- 4. obtain medication history interview and counsel the patients
- 5. identify drug related problems
- 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.

Unit I:

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 detecting titute of Pharmac

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10 Hours

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drug 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

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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 8 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 7 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

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c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

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.
- 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.
- 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.
- 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)

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BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

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 issuesrelated 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 tohealth and pharmaceutical issues

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

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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):

- Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
- Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
- Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
- 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

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BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and 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;

- 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 content:

Unit I 10Hours

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 10Hours

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 India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III 10Hours

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 e of Pharmacautica

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Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV 08Hours

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 07Hours

Regulatory Concepts

Basic terminology, 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.
- 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.
- New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
- Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
- FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
- 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

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES TIME - TABLE FOR THE ACADAMIC YEAR: 2022-2023 Time Table for B. Pharmacy I Year I Sem (Section-A) BOLLIKUNTA, WARANGAL - 506 005

01.45pm-4.30pm (Practical)	Batch-II	Human Anatomy and Physiology - I	Pharmaceutical Inorganic Chemistry	Library	Pharmaceutical Analysis I	Pharmaceutics-I	Communication Skills
01.45p	Batch - I	Pharmaccutical Inorganic Chemistry	Library	Human Anatomy and Physiology - I	Pharmaceutics-I	Communication	Pharmaccutical Analysis I
01.10pm-	mdc+.10	1	D	z		U	π
12.20pm-01.10pm		Pharmaceutical Analysis I	Pharmaceutics I	Pharmaceutical Inorganic Chemistry (Tutorial)	Pharmaccutics I	Remedial Biology/ Mathematics	Human Anatomy and Physiology – I (Tutorial)
11.30am-12.20pm		Library	Library	Remedial Biology/ Mathematics	Pharmaceutical Analysis I (Tutorial)	Pharmaceutical Inorganic Chemistry	Remedial Biology/ Mathematics
10.40am-11.30am		Communication skills	Human Anatomy and Physiology - I	Pharmaccutical Analysis I	Human Anatomy and Physiology - I	Pharmaceutics I (Tutorial)	Pharmaccutical Inorganic Chemistry
9.50am-10.40am		Pharmaceutical Inorganic Chemistry	Communication skills	Pharmaceutics I	Communication skills	Human Anatomy and Physiology - I	Pharmaceutical Analysis I
DAY		Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Human Anatomy and Physiology - I Pharmaccutical Analysis I

Pharmaceutics I

Pharmaceutical Inorganic Chemistry

Communication skills Remedial Biology/ Mathematics

Dr. G. Praneeth Dr. K. Rathnakar Reddy

Dr. V. Padmaja Dr. Yakaiah Ms. V. Sheerisha Ms. P. Jeevitha

Vaagdevi Institute of Pharmaceutical Science Principal.

Bollikunta, Warangal. Telangana 506 nn

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES Time Table for B.Pharmacy I Year II Semester (Section A) TIME – TABLE FOR THE ACADAMIC YEAR: 2022-2023 BOLLIKUNTA, WARANGAL – 506 005

tal Computer Human Anatomy and Applications Physiology - II L Biochemistry Human Anatomy and Physiology - II U Ph Computer Pathophysiology - II U Ph Computer Pathophysiology - II U Ph Computer Pathophysiology - II U Ph Human Anatomy Pharmaceutical C Pharmaceutical and Physiology - Organic Chemistry I II(Tutorial) Pharmaceutical Pharmaceutical Pharmaceutical Pharmaceutical II(Tutorial) Pharmaceutical Pharmaceutical Pharmaceutical Pharmaceutical II(Tutorial) Pharmaceutical Pharmaceutical Pharmaceutical II(Tutorial) Pharmaceutical Pharmaceutical Pharmaceutical II(Tutorial) Pharmaceutical Pharmaceutical Pharmaceutical Pharmaceutical Pharmaceutical Pharmaceutical II(Tutorial) Pharmaceutical P	DAY	9.50am-10.40am	10.40am-	11.30am-12.20pm	12.20pm-01.10pm	01.10pm-	01.45pm-4.30	01.45pm-4.30pm (Practical)
Biochemistry Pathophysiology Library/ Sports Pharmaceutical Organic Chemistry I Pharmaceutical Organic Chemistry I Pharmaceutical Organic Chemistry I Pharmaceutical Organic Chemistry I Pharmaceutical Applications Pharmaceutical Sciences Applications Pathophysiology Biochemistry Pharmaceutical Biochemistry Organic Chemistry I II(Tutorial) Pharmaceutical Sciences Biochemistry Computer Applications Computer						01.45pm	Batch- I	Batch - II
Pathophysiology Library/ Sports Pharmaceutical Pharmaceutical Anatomy and Chemistry I Pharmaceutical Chemistry I Physiology - II Applications Sciences I Trutorial) Pharmaceutical Chemistry I Intruorial Pathophysiology - II Pharmaceutical Chemistry I Intruorial Pharmaceutical Sciences I Intruorial Pharmaceutical Pharmaceutical Sciences I Intruorial Pharmaceutical Pharmaceutical Sciences I Intruorial Pharmaceutical Pharmaceutic	Monday	Biochemistry	Environmental sciences	Computer Applications	Human Anatomy and Physiology - II	_	Pharmaceutical Organic	Human Anatomy and
Pharmaceutical Anatomy and Computer Chemistry I Physiology - II Computer Chemistry I Physiology - II Physiology - II Physiology - II Physiology - II Computer Sciences Applications	Tuesday	Pathophysiology	Library/ Sports	Biochemistry (Tutorial)	Human Anatomy and Physiology - II	2 ;	Human Anatomy and	Physiology - II Pharmaceutical Organic
Chemistry I	Vednesday		Human			5	Physiology - II	Chemistry I
Environmental sciences Computer Applications Library/ Sports Pharmaceutical Organic Chemistry I Computer Library/ Sports Pathophysiology Sciences Biochemistry Organic Chemistry Organic Chemistry I(Tutorial) Pathophysiology Library/ Sports Library/ Sports	cancounty		Anatomy and Physiology - II	Computer Applications	Pathophysiology (Tutorial)	,	Computer	Library/ Sports
Pathophysiology Biochemistry Human Anatomy Pharmaceutical Biochemistry Organic Chemistry I Human Anatomy Pharmaceutical Biochemistry Organic Chemistry I Harmaceutical Sciences II(Tutorial) Pharmaceutical Biochemistry Organic Chemistry I Harmaceutical Biochemistry II(Tutorial) Pharmaceutical Biochemistry II(Tutorial) Pharma	Fhursday	Environmental	Computer	I showing Concession	Pharmaceutical	Z.		
Pathophysiology Biochemistry Human Anatomy and Physiology - II(Tutorial) Pharmaceutical Biochemistry Organic Chemistry I Pharmaceutical Sciences I(Tutorial) I(Tutorial) Pharmaceutical Pharmaceutical Sciences I(Tutorial)		sciences	Applications	Library, Sports	Organic Chemistry I		Library/ Sports	Applications
Environmental Biochemistry Organic Chemistry I(Tutorial)	Friday	Pathophysiology	Biochemistry	Human Anatomy and Physiology - II(Tutorial)	Pharmaceutical Organic Chemistry I	ပ	Biochemistry	Library/ Sports
Sciences Biochemistry Organic Chemistry Pathophysiology Library/ Sports I(Tutorial)	abinday			Pharmaceutical		H		
	, and and	sciences	Biochemistry	Organic Chemistry I(Tutorial)	Pathophysiology		Library/ Sports	Biochemistry

Pharmaceutical Organic Chemistry I Human Anatomy and Physiology - II Biochemistry

Mr. G. Sreejarani Dr. T. Sravanthi

Computer Applications Pathophysiology

Environmental sciences

Dr. M. Radhakishan Dr. V. Mouna reddy Mrs. S. Deepthi Mrs. Anitha

Vaagdevi Institute of Pharmaceutical Science Bollikunta, Warangal. Telangana 506 005 Principal

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES TIME - TABLE FOR THE ACADAMIC YEAR: 2022 - 2023 Time Table for B. Pharmacy III Year I Semester (Section-A) BOLLIKUNTA, WARANGAL - 506 005

DAY	9.50am-10.40am	10.40am-11.30am		11.30ат-12.20рт 12.20рт-01.10рт	01.10pm- 01.45pm	1.45pm (Pra	1.45pm-4.30pm (Practical)
				The second secon		Batch - I	Batch - II
Monday	Pharmaceutical Jurisprudence	Pharmacognosy and Phytochemistry II	Library/ Tutorial	Pharmacology II	-	Industrial Pharmacy I	Library
Tuesday	Pharmacognosy and Phytochemistry II	Pharmaceutical Jurisprudence	Medicinal Chemistry II (Tutorial)	Library/ Tutorial	2	Library	Industrial Pharmacy I
Wednesday	Medicinal Chemistry II	Industrial Pharmacy I	Pharmacognosy & Phytochemistry II (Tutorial)	Pharmaceutical Jurisprudence (Tutorial)	n	Pharmacognosy and Phytochemistry II	Library
Thursday	Medicinal Chemistry II	Industrial Pharmacy I	Pharmacology II (Tutorial)	Library/Tutorial	z	Library	Pharmacognosy and
Friday	Industrial Pharmacy I	Medicinal Chemistry II	Pharmacognosy and Phytochemistry II (Tutorial)	Pharmacology II	C	Pharmacology II	Phytochemistry II Library
Saturday	Pharmacology II	Pharmaceutical Jurisprudence	Library/Tutorial	Industrial Pharmacy I (Tutorial)	H	Library	Pharmacology II

Medicinal Chemistry II Industrial Pharmacy I

Mrs. Komal Ksherasagar

M. Sandhyarani Dr. N. Nishitha

Ms. S. Sabitha Dr. C. Vijitha

Pharmacology II

Pharmacognosy and Phytochemistry II The of Pharmers of Pharmaccutieal Jurisprudence

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES

TIME - TABLE FOR THE ACADAMIC YEAR: 2022- 2023 Time Table for B. Pharmacy IV Year I Semester (Section-A) BOLLIKUNTA, WARANGAL - 506 005

DAY	9.50am-10.40am	10.40am-11.30am	10.40am-11.30am 11.30am-12.20pm 12.20pm-01.10pm	12.20pm-01.10pm	-md01.10	1.45pm (Prac	1.45pm-4.30pm (Practical)
					L.45pm	Batch -I	Batch-II
Monday	Pharmacy Practice	Practice School	Novel Drug Delivery System	Instrumental Methods of Analysis	٦	Practice	Practice School
Tuesday	Industrial Pharmacy – II	Novel Drug Delivery System (Tutorial)	Practice School	Pharmacy Practice	=	Practice School	Instrumental Methods of
Wednesday	Instrumental Methods of Analysis	Practice School	Novel Drug Delivery System	Industrial Pharmacy – II (Tutorial)		Instrumental Methods of Analysis	Practice School
Thursday	Pharmacy Practice	Industrial Pharmacy – II	Practice School	Instrumental Methods of Analysis (Tutorial)	z	Practice School	School
Friday	Instrumental Methods of Analysis	Pharmacy Practice (Tutorial)	Practice School	Practice School	C	Practice School	School
Saturday	Novel Drug Delivery System	Practice School	Industrial Pharmacy – II	Practice School	Ξ	Practice School	School

Mrs. A. Phanedra Instrumental Methods of Analysis

Mrs.P.Jeevitha

Mrs. M Sandhya Rani Ms. Rahematunnisa

Novel Drug Delivery System

Practice School* e of Pharm

Industrial Pharmacy - II Pharmacy Practice Respective guides

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VAAGDEVI INSTITUTE OF PHARMACEUTICAL SCIENCES Time Table for B. Pharmacy IV Year II Semester (Section A) TIME - TABLE FOR THE ACADAMIC YEAR: 2022-2023 BOLLIKUNTA, WARANGAL - 506 005

DAY	9,50am-10,40am	10.40am-11.30am	11.30ат-12.20рт	12.20pm-01.10pm	01.10pm-	1.45pm (Prac	1.45pm-4.30pm (Practical)
					mderer	Batch -I	Batch - I Batch-II
Monday	Cosmetics science	Social & preventive pharmacy	Project work	Biostatistics & Research Methodology	1	Project	Project Work
Tuesday	Project work	Project work	Biostatistics & Research Methodology	Pharmacovigilance		Project Work	Work
Wednesday	Pharmacovigilance	Project work	Social & preventive	Cosmetics science	2	Project Work	Work
Thursday	Project work	Cosmetics science	Biostatistics & Research Methodology	Project work	z	Project Work	Work
Friday	Social & preventive pharmacy	Cosmetics science	Project work	Pharmacovigilance		Project Work	Work
Saturday	Biopharmaceutics and Pharmacokinetics (Tutorial)	Hospital and Clinical Pharmacy	Pharmaccutical Biotechnology	Pharmacovigilance	O H	Project Work	Work

Biostatistics & Research Methodology

Social & preventive pharmacy

Cosmetics science Project Work

Mrs. B. Sharanya Dr. K. Naresh

M. Ranadheer kumar

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