

K. K. WAGH COLLEGE OF PHARMACY

(B. Pharmacy & D. Pharmacy)

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(Affiliated to Dr. Babasaheb Ambedkar Technological University, Lonere, MSBTE, Mumbai & Approved by PCI)

1.3.2

Number of courses that include experiential learning through project work/ field work/internships during the year

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]



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.



Course that include experiential learning through project work/ field work/internships during the year 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		Maximum	
	Ma	arks	
Attendance (Refer Table – XII)	4	2	
Academic activities (Average of any 3 activities e.g. quiz, assignment,	3	15	
open book test, field work, group discussion and seminar)	5	1.5	
Student – Teacher interaction	3	1.5	
Total	10	5	
Practical			
Attendance (Refer Table – XII)	2		
Based on Practical Records, Regular viva voce, etc.	3		
Total	5		

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

Percentage of Attendance	Theory	Practical
95 - 100	4	2
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)	=	$10 \ge 1 = 10$
OR		OR
Objective Type Questions (5 x 2)	=	$05 \ge 2 = 10$
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	$1 \ge 10 = 10$
II. Short Answers (Answer 2 out of 3)	=	$2 \ge 5 = 10$
SOLLEGE OF OTHER	Total =	30 marks

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

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) theCGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

CGPA = $\begin{array}{c} C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8 \\ \hline C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8 \end{array}$

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



Evaluation of Dissertation Book:		
Objective(s) of the work d	one	15 Marks
Methodology adopted		20 Marks
Results and Discussions		20 Marks
Conclusions and Outcomes	8	20 Marks
	Total	75 Marks
Evaluation of Presentation:		
Presentation of work		25 Marks
Communication skills		20 Marks
Question and answer skills	i -	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.



Course that include experiential learning through project work/ field work/internships during the year BP 502 T. Industrial PharmacyI (Theory)

45 Hours

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

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

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

Course content:

3 hours/ week

UNIT-I

07 Hours

10 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia



BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

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

Course Content:

7 Hours

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

UNIT-I

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium, Phenvlpropanoids and Flavonoids: Lignans, Tea, Ruta Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander, Tannins: Catechu, Pterocarpus Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony Glycosides: Senna, Aloes, Bitter Almond Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrhetinic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

UNIT-IV

10 Hours Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol. Vincristine and Vinblastine



UNIT V

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

14 Hours

06 Hours

8 Hours

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT –I

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

10 Hours

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

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

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

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

Course Content:

UNIT-I

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III

Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

10 Hours

10 Hours



10 Hours