

# 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]

PURAN MURTI

#### **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

#### First year B. Pharm:

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

#### 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.

#### 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.

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#### **Credit assignment**

#### **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 andone 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.

#### 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.

#### 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.

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Table-I: 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 Pharmacyl- 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 Pharmacy I – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	27	5	26

Table-II: Semester wise credits distribution

Semeste <mark>r</mark>		Credit Points
ı		2 <mark>7/</mark> 29 <sup>\$</sup> /30 <sup>#</sup>
II		29
III		26
IV	DITDAN	28
V	T CAROLINA	26
VI		26
VII	10911	24
VIII	A STATE OF THE PARTY OF THE PAR	<mark>2</mark> 2
Extracurricular/ Co curricular activities		01*
Total credit points for the program		209/211\$/212#

<sup>\*</sup> 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.

#### 10. Program Committee

- 1. The B. Pharm. program shall have a Program Committee constituted by the Headof 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.

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<sup>\$</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

<sup>\*</sup>Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

#### 3. Duties of the Program Committee:

- i. Periodically reviewing the progress of the classes.
- ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
- iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
- iv. Communicating its recommendation to the Head of the institution on academic matters.
- v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessional exam (Internal Assessment) and before the endsemester exam.

#### 11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – End semester examinations

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

#### Semester V

0		Internal Assessment			End Semester Exams			
Course code	Name of the cou <mark>r</mark> se	Continu	Session	al Exams Total		Marks	Duration	Total Mark
Code		ous	Marks	Duratio	Total	Walks	Duration	S
		Mod		n				
		е	ATAT					
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	<mark>7</mark> 5	3 Hrs	100
BP502T	Industrial Pharmacyl– Theory	10	15	1 Hr	25	<b>7</b> 5	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	<b>7</b> 5	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence -	10	15	1 Hr	25	75	3 Hrs	100
БРЭОЭТ	Theory	10	15	1 111	25	75	3 HIS	100
BP506P	Industrial Pharmacyl- Practical	5	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		105	17 Hr	170	480	27 Hrs	650

#### Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall beawarded as per the scheme given below.

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Table-IV: Scheme for awarding internal assessment: Continuous mode

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

Table- V: 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 
$$= 10 \times 1 = 10$$
 $(MCQs)OR$ 

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

Total  $= 30 \text{ marks}$ 



# For subjects having Non University Examination

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

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Total = 30 marks

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#### Question paper pattern for practical sessional examinations

I. Synopsis = 10

II. Experiments = 25
III. Viva voce = 05

Total = 40 marks

#### 1. 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.

#### 2. Carry forward of marks

In case a student fails 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 Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

#### 3. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in 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.

#### 4. Re-examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table VI The exact dates of examinations shall be notified from time to time.

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Table-VI: Tentative	SCHARIIIA At	and camactar	Avaminatione
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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 For75 marks paper

I. Multiple Choice Questions(MCQs) =  $20 \times 1 = 20$ OR Objective Type Questions (10 x 2) =  $10 \times 2 = 20$ 

(Answer all the questions)

II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

Total = 75 marks

#### For 50 marks paper

I. Long Answers (Answer 2 out of 3) = 2 x 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 x 10 =10 II. Short Answers (Answer 5 out of 7) = 5 x 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



#### 11. 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 hasgiven 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.

Note: Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

#### 17. Grading of performances

#### 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 – VII.

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Table – VII: 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	С	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 A Band 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 in 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 = 
$$C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5$$
  
 $C_1 + C_2 + C_3 + C_4 + C_5$ 

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 ABS grade 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:

**SGPA =** 
$$C_1G_1 + C_2G_2 + C_3G_3 + C_4^* ZERO + C_5G_5$$
  
 $C_1 + C_2 + C_3 + C_4 + C_5$ 

#### 17. Cumulative Grade Point Average (CGPA)

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



$$CGPA = C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8$$

$$C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8$$

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,....

#### 19. 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

#### 20. Project work

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

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

#### **Evaluation of Dissertation Book:**

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

Total 75 Marks

#### **Evaluation of Presentation:**

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

Total 75 Marks

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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.



#### 21. 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.

#### 22. Practice School

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

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

#### 23. 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.

#### 24. Award of degree

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

#### 25. Duration for completion of the program of study

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

#### 26. 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 condo nation fee.

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

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#### SEMESTER V

#### **BP501T. MEDICINAL CHEMISTRY – II (Theory)**

45 Hours

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

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

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

#### Course

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

UNIT- I 10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H₁-antagonists: Diphenhydramine hydrochloride\*, Dimenhydrinate. Clemastine fumarate. Doxylamines Diphenylphyraline hydrochloride. cuccinate. hydrochloride. Meclizine Tripelenamine hydrochloride. Chlorcyclizine hydrochloride. Buclizine hydrochloride. Chlorpheniramine Triprolidine maleate. hvdrochloride\*. Phenidamine tartarate. Promethazine hydrochloride\*, Trimeprazine Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

**H**<sub>2</sub>**-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

**Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole Anti-neoplastic agents:

**Alkylating agents:** Meclorethamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

**Antimetabolites:** Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin **Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane

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#### **Anti-anginal:**

**Vasodilators:** Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbidedinitrite\*, Dipyridamole.

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III 10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

**Coagulant & Anticoagulants**: Menadione, Acetomenadione, Warfarin\*, Anisindione, clopidogrel

**Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT- IV 08 Hours

#### **Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

**Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

**Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone,

Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

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UNIT – V 07 Hours

#### **Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides:

Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine,

Piperocaine.

Amino Benzoic acid derivatives: Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine,

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Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.\*

#### Recommended Books (Latest Editions)

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

#### **BP 502 T. Industrial Pharmacyl (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
- 2. Know various considerations in development of pharmaceutical dosage forms
- 3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.

#### **Course content:**

3 hours/ week

#### UNIT-I

**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, polymerizationBCS 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**

## CAMPUS

10 Hours

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#### Tablets:

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

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

UNIT-III 08 Hours

#### Capsules:

a. *Hard gelatin capsules:* Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

**Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV 10 Hours

#### Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusionfluids.
   Quality control tests of parenteral products.

**Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V 10 Hours

**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

**Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

**Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

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#### **BP 506 P. Industrial Pharmacyl (Practical)**

4 Hours/week

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

#### Recommended Books: (Latest Editions)

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

#### **BP503.T. PHARMACOLOGY-II (Theory)**

45 Hours

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

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

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

#### **Course Content:**

#### **UNIT-I**

- 1. Pharmacology of drugs acting on cardio vascular system
  - a. Introduction to hemodynamic and electrophysiology of heart.
  - b. Drugs used in congestive heart failure
  - c. Anti-hypertensive drugs.
  - d. Anti-anginal drugs.
  - e. Anti-arrhythmic drugs.
  - f. Anti-hyperlipidemic drugs.

#### **UNIT-II**

## 10hours

- 1. Pharmacology of drugs acting on cardio vascular system
  - a. Drug used in the therapy of shock.
  - b. Hematinics, coagulants and anticoagulants.
  - c. Fibrinolytics and anti-platelet drugs
  - d. Plasma volume expanders
- 2. Pharmacology of drugs acting on urinary system
  - a. Diuretics
  - b. Anti-diuretics.

#### **UNIT-III**

#### 10hours

10hours

#### 3. Autocoids and related drugs

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

Campus:

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#### **UNIT-IV**

08hours

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#### 5. Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V 07hours

#### 5. Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

#### 6. Bioassay

- a. Principles and applications of bioassay.
- B. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamineand 5-HT



#### **BP 507 P. PHARMACOLOGY-II (Practical)**

4Hrs/Week

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- 1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heart rate of dog.
- 4. Study of diuretic activity of drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- 6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
- 7. Bioassay of histamine using guinea pig ileum by matching method.
- 8. Bioassay of oxytocin using rat uterine horn by interpolation method.
- 9. Bioassay of serotonin using rat fundus strip by three point bioassay.
- 10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
- 11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schilds plot method).
- 12. Determination of PD2 value using guinea pig ileum.
- 13. Effect of spasmogens and spasmolytics using rabbit jejunum.
- 14. Anti-inflammatory activity of drugs using carrageenan induced paw-edemamodel.
- 15. Analgesic activity of drug using central and peripheral methods

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

#### Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill.
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
- 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
- 6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
- 9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan

#### 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:**

UNIT-I Hours 7

#### 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 Hours

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

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaguinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III 06
Hours

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid & Rutin

c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine

d) Resins: Podophyllotoxin, Curcumin

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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 8
Hours

#### **Basics of Phytochemistry**

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



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## BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical) 4 Hours/Week

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

#### Recommended Books: (Latest Editions)

- W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9. Pharmacognosy & Pharmacobiotechnology, James Bobbers, Marilyn KS, VE Tylor.

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- 10. The formulation and preparation of cosmetic, fragrances and flavours.
- 11. Remington's Pharmaceutical sciences.
- 12. Text Book of Biotechnology by Vyas and Dixit.
- 13. Text Book of Biotechnology by R.C. Dubey.



#### BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

- 1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- 2. Various Indian pharmaceutical Acts and Laws
- 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 andRules

Import of drugs – Classes of drugs and cosmetics prohibited from import, 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 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 EssentialMedicines (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

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



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