



**Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru**

Curriculum design, continuous and formative assessment evaluation of
B. Pharm. course of Semester & w.e.f Academic year 2019-20

**SEMESTER-V
BP501T: Medicinal Chemistry II (Theory)**

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.

Departmental objectives (what the learners will be able to perform after completing the subject):

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

- i. Understand the chemistry of drugs with respect to their pharmacological activity
- ii. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- iii. Know the Structural Activity Relationship (SAR) of different class of drugs
- iv. Write the chemical synthesis of selected drugs

Annual objectives (for each year, if the subject is spread over different years): **NA**

Content distribution as per the list of topics, time allotted for each topic, distribution for 'Must know', 'Desirable to know' and 'Nice to know' and the probable Weightage.

The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Sl No`	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
UNIT-I	ANTI-HISTAMINIC AGENTS	10	<p>H₁-Antagonists: Diphenhydramine HCl*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine HCl, Chlorcyclizine HCl, Meclizine HCl, Buclizine HCl, Chlorpheniramine maleate, Triprolidine HCl *, Phenidamine tartarate, Promethazine HCl *, Cyproheptadine HCl Trimeprazine tartrate, , Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium</p> <p>H₂-Antagonists: Cimetidine*, Famotidine, Ranitidin.</p> <p>Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole..</p> <p>ANTI-NEOPLASTIC AGENTS:</p> <p>Alkylating agents: Meclorothamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa</p> <p>Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine</p> <p>Antibiotics: Dactinomycin,</p>	<p>Histamine, receptors and their distribution in the human body General Mechanism of action of antihistaminic and antineoplastic agents. Medicinal uses.</p>	<p>Structure, biosynthesis and biological importance of Histamine History and development of antihistaminic agents, anti-neoplastic agents. Proton pump inhibitors. Adverse effects and possible side effects and dosage of the above mentioned drugs</p>	21 Marks

			Daunorubicin, Doxorubicin, Bleomycin Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate Miscellaneous: Cisplatin, Mitotane.			
UNIT-II	ANTI-ANGINAL	10	Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole. Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. DIURETICS: Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol ANTI-HYPERTENSIVE AGENTS: Timolol, Captopril, Lisinopril, Enalapril, Benazepril HCl, Quinapril HCl, Methyldopate HCl,* Clonidine HCl, Guanethidine monosulphate,	Histamine, receptors and their distribution in the human body General Mechanism of action of antihistaminic and antineoplastic agents. Medicinal uses.	Brand names, Patent, Adverse effects, possible side effects and dosage of the above mentioned drugs	21 Marks

			Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.			
UNIT-III	ANTI-ARRHYTHMIC DRUGS	10	Quinidine sulphate, Procainamide HCl, Disopyramide phosphate*, Phenytoin sodium, Lidocaine HCl, Tocainide HCl, Mexiletine HCl, Lorcainide HCl, 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.	Mechanism of action, uses of all classes	Brand names, Etiology of various cardiovascular diseases, Patent names, Adverse effects and possible side effects and dosage of the above mentioned drugs	19 Marks
UNIT-IV	Drugs acting on Endocrine system	8	Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol. Drugs for erectile dysfunction: Sildenafil, Tadalafil. Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone Thyroid and antithyroid drugs: L-	Nomenclature, Stereochemistry and metabolism of steroids. Mechanism of action and specific side effects of drugs.	Brand names, Patent names, Adverse effects and possible side effects and dosage of some clinically used drugs	17 Marks

			Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.			
UNIT-V	ANTIDIABETIC AGENTS	7	<p>Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.</p> <p>Biguanides: Metformin.</p> <p>Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide.</p> <p>Glucosidase inhibitors: Acarbose, Voglibose.</p> <p>LOCAL ANESTHETICS:</p> <p>Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.</p> <p>Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.</p> <p>Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.</p> <p>Miscellaneous: Phenacaine, Dipiperodon, Dibucaine.*</p>	Insulin and its preparations Mechanism of action and specific side effects of drugs.	Brand names, Patent names, Adverse effects and possible side effects and dosage of some clinically used drugs.	17 Marks

2. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

BLUE PRINT OF MODEL QUESTION PAPER								
BP501T: Medicinal Chemistry-II								
TIME: 3 HOURS					MAX. MARKS: 75			
Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	1	1	2	-	-	1	21
Unit-II	10	1	1	2	-	-	1	21
Unit-III	10	-	3	-	-	-	2	19
Unit-IV	08	-	2	-	-	1	1	17
Unit-V	07	1	1	1	-	-	-	17
Total	45	30	40	10	-	5	10	95
		80			15			95

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to Know area of the Curriculum.

3. Question paper layout to show which question number will represent which chapter (s)

Long Essay:**2X 10 = 20**

1	Define and Classify antihistaminic agents with suitable examples and explain the synthesis and medicinal uses of Diphenhydramine HCl and Promethazine HCl.
2	Define and classify diuretics with examples. Explain the Mechanism of action of Loop diuretics and explain the synthesis of Furosemide.
3	Define and Classify Local anesthetics with suitable examples and add a note on SAR of benzoic acid derivatives.

Short Essays:**5x 7 = 35**

4	Classify alkylating agents with examples. Outline the synthesis of Mechlorethamine.
5	Explain a note on Antianginal agents and explain the synthesis of Nitroglycerin.
6	What are antiarrhythmic drugs? Write the structure and uses of Quinidine, Procainamide HCl, Phenytoin sodium and Amiodarone.
7	Write a note on Anti-hyperlipidemic agents
8	What are Coagulants and anticoagulants? Explain the synthesis and uses of Warfarin
9	Write the structure and uses of Testosterone, Diethyl stilbestrol, Esterone, Prednisolone and Dexamethasone
10	Write a note on thyroid and antithyroid drugs
11	Explain the metabolism of steroids
12	Define and classify antidiabetic drugs with examples and write the synthesis of Tolbutamide

Short Answers:**2X10 = 20**

13	What are Gastric proton pump inhibitors and give the structure of any one.
14	Write the synthesis and uses of Mercaptopurine
15	Write the Mechanism of action of natural antineoplastic agents.
16	Write the synthesis of Methyldopate HCl.
17	Write the structures of any two calcium channel blockers.
18	Write the structure and uses of Minoxidil and Hydralazine HCl.
19	Write the synthesis of Disopyramide Phosphate.
20	Write the structure and uses of any one drug used in Congestive heart failure.
21	Write the structure and uses of Sildenafil
22	Write the synthesis of Dibucaine.

4. Scheme of Practical / Clinical Teaching and Assessment:

List the expected practical / clinical competencies.

State the objectives for each competencies.

Assign content for the objectives.

Describe the teaching – learning process

Sl No	Skills	Duration	Learning methods

Scheme of examination with the distribution of marks as per the prioritisation of competencies.

Sl No	Competency	Assessment criteria	Marks

8. Suggested references (as per APA style):

- Basic references
- Advanced references (may also include journals / web / other electronic sources)

BP 502T Industrial Pharmacy (Theory)**5th Semester B.Pharm****45 Hours**

Sl. No.	Topic	Hours	Learning content distribution			Weightage (Marks)
			Must know	Desirable to know	Nice to know	
Unit I	Preformulation studies	07	Introduction to Preformulation, goals and objectives, study of physicochemical characteristics of drug substances. Applications of Preformulation consideration in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	Physical form. Physical form (Crystal and amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, Partition coefficient), polymorphism. BCS classification of drugs and its significance	Chemical properties: Hydrolysis, oxidation, reduction, racemisation, polymerization.	14
Unit-II	Tablets	06	Introduction, classification of tablets, Formulation of tablets, granulation methods, compression and processing problems, and quality control tests of tablets.	Tablet coating, types of coating, coating materials, formulation of coating composition, methods of coating and equipment employed and defects in coating	tablet excipients example, In process quality control tests of tablets	22

	Liquid orals	04	Formulation and manufacturing consideration of syrups and elixirs, suspension and emulsions	Filling and packaging, evaluation of liquid orals (as per pharmacopeia)	---	
Unit III	Capsules	08	Hard gelatine capsule: Introduction, Production. Size of capsule, filling, finishing and special techniques of hard gelatine capsules, quality control tests for capsules.	Manufacturing defects of hard gelatine 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. Pellets: Introduction, formulation requirement, pelletization process	Packin and storage and stability testing of soft gelatine capsule and their applications. Equipments for manufacture of pellets	19

Unit-IV	Parenteral Products	10	Definition, types, advantages and limitations. Vehicles, additives, importance of isotonicity. Production procedure, production facility and controls, aseptic processing.	Preformulation factors and essential requirements of parenterals. Formulation of injections, sterile powders, large volume parenterals.	Formulation of lyophilized product, emulsion and suspensions.	21
	Ophthalmic preparations:		Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Introduction, formulation consideration, formulation of eye drops, eye ointment and eye lotions, methods of preparation.	Quality control tests for parenterals Labelling, containers. Evaluation of ophthalmic preparations.		
Unit-V	Cosmetics	10	Formulation and preparation of lipsticks, shampoos, cold cream and vanishing cream, tooth paste. suspensions, emulsions and solutions. Stability of these preparations	Hair dyes, sunscreens.	Stability aspects of packaging materials	19
	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 sceinecs.		Materials used for packaging of pharmaceutical products, Quality control tests.	Factors influencing choice of containers, Legal and official requirements for containers		
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1. Blueprint of question paper, for each QP. This shows the Weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject. The following template demonstrates how each QP Blueprint would look like:

Unit No.	Chapter	Marks distribution					Total Marks
		Must Know	Desirable to Know	Long Essay	Short Essay	Short Answer	
Unit-I	Preformulation studies	Introduction to Preformulation, goals and objectives, study of physicochemical characteristics of drug substances. Applications of Preformulation consideration in the development of solid, liquid oral and parenteral dosage forms and its impact on stability	Physical form. Physical form (Crrystal and amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, Partition coefficient), polymorphism. BCS classification of drugs and its significance	--	5+5	2+2	14

		of dosage forms.					
Unit-II	Tablets	<p>Introduction, classification of tablets, Formulation of tablets, granulation methods, compression and processing problems, and quality control tests of tablets.</p> <p>Formulation and manufacturing consideration of syrups and elixirs, suspension and emulsions</p>	<p>Tablet coating, types of coating, coating materials, formulation of coating composition, methods of coating and equipment employed and defects in coating</p> <p>Filling and packaging, evaluation of liquid orals (as per pharmacopeia)</p>	10	5+5	2	22
Unit-III	Capsules	<p>Hard gelatine capsule: Introduction, Production. Size of capsule, filling, finishing and special techniques of hard gelatine capsules, quality control tests for capsules.</p>	<p>Manufacturing defects of hard gelatine 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.</p> <p>Pellets: Introduction, formulation requirement, pelletization process</p>	10	5	2+2	19

	Parenteral Products	Definition, types, advantages and limitations. Vehicles, additives, importance of Isotonicity. Production procedure, production facility and controls, aseptic processing.	Preformulation factors and essential requirements of parenterals. Formulation of injections, sterile powders, large volume parenterals. Quality control tests for parenterals				
	Ophthalmic preparations	Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Introduction, formulation consideration, formulation of eye drops, eye ointment and eye lotions, methods of preparation.	Labelling, containers. Evaluation of ophthalmic preparations.	10	5	2+2+2	21
Unit-V	Cosmetics	Formulation and preparation of lipsticks, shampoos, cold cream and vanishing cream, tooth paste. Suspensions, emulsions and solutions. Stability of these preparations	Hair dyes, sunscreens.	--	5+5+5	2+2	19

	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	Materials used for packaging of pharmaceutical products, Quality control tests.	Factors influencing				
	Total			30	45	20	95

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to know area of the Curriculum.

2. Question paper layout to show which question number will represent which chapter (s)

BP 502 T Industrial Pharmacy (Theory)

5th Semester B. Pharm

TIME: 3 HOURS

MAX. MARKS: 75

Long Essay:

$$2 \times 10 = 20$$

1	Tablets
2	Capsules
3	Parenteral Products

Short Essays:

$$5 \times 9 = 45$$

4	Preformulation studies
5	Tablets and Liquid orals
6	Capsules
7	Parenteral Products and Ophthalmic formulations
8	Cosmetics, Pharmaceutical aerosols and packaging material science

Short Answers:

$$2 \times 10 = 20$$

9	Preformulation studies
10	Tablets and Liquid orals
11	Capsules
12	Parenteral Products and Ophthalmic formulations
13	Cosmetics, Pharmaceutical aerosols and packaging material science

BLUE PRINT OF MODEL QUESTION PAPER of 5th Sem INDUSTRIAL PHARMACY

Chapter No.	Name of the Chapter	Hours Allotted	Must Know			Desire to Know			Weightage of Marks
			10	5	2	10	5	2	
Unit-I	Preformulation studies	07	-	5	2	-	5	2	14
Unit-II	Tablets and Liquid orals	10	10	5	2	-	5	-	22
Unit-III	Capsules	8	10	5	2	-	-	2	19
Unit-IV	Parenteral Products and Ophthalmic formulations	10	10	5	4	-	-	2	21
Unit-V	Cosmetics, Pharmaceutical aerosols and packaging material science	10	-	10	2	-	5	2	19
	TOTAL	45	30	30	12	-	15	8	95

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Curriculum delivery design of B. Pharm. course of Semester V
w.e.f Academic year 2019-20

SEMESTER-V

BP503T PHARMACOLOGY-II (Theory)

Sl No`	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
UNIT-I	Pharmacology of drugs acting on cardio vascular system	10	Introduction to hemodynamic and electrophysiology of heart. Drugs used in congestive heart failure Anti-hypertensive drugs. Anti-hyperlipidemic drugs.	Anti-anginal drugs. Anti-arrhythmic drugs.		22
UNIT-II	Pharmacology of drugs acting on cardio vascular system and urinary system	10	Drug used in the therapy of shock. Hematinics, coagulants and anticoagulants. Anti-platelet drugs Diuretics	Anti-diuretics, Fibrinolytics	Plasma volume expanders	21
UNIT-III	Autocoids and related drugs		Introduction to autacoids and classification Histamine, Prostaglandins Non-steroidal anti-inflammatory agents Antirheumatic drugs	Anti-gout drugs, Bradykinin 5-HT and their antagonists. Angiotensin, Thromboxanes and Leukotrienes.	Substance P.	19

UNIT-IV	Pharmacology of drugs acting on endocrine system	8	<p>Basic concepts in endocrine pharmacology.</p> <p>Anterior Pituitary hormones- analogues and their inhibitors.</p> <p>Thyroid hormones- analogues and their inhibitors.</p> <p>Insulin, Oral Hypoglycemic agents and glucagon.</p>	<p>ACTH and corticosteroids</p> <p>Hormones regulating plasma calcium level- Vitamin-D, Parathormone,</p>	Calcitonin	19
UNIT-V	Pharmacology of drugs acting on endocrine system and Bioassay	7	<p>Estrogens, progesterone and oral contraceptives.</p> <p>Drugs acting on the uterus.</p> <p>Principles and applications of bioassay</p> <p>Types of bioassay</p> <p>Bioassay of insulin, oxytocin, vasopressin, d-tubocurarine, digitalis, histamine</p>	<p>Bioassay of ACTH, Androgens and Anabolic steroids.</p>	Bioassay of 5-HT	14

Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

BLUE PRINT OF MODEL QUESTION PAPER								
BP503.T. PHARMACOLOGY-II (Theory)								
TIME: 3 HOURS MAX. MARKS: 75								
Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X4)	SE (5X5)	SA (2X6)	LE (10X0)	SE (5X2)	SA (2X4)	
Unit-I	10	1	1	1	-	1	-	22
Unit-II	10		2	1	-	-	2	21
Unit-III	10	1	2	1	-	-	1	19
Unit-IV	08	-	2	2	-	1	-	19
Unit-V	07	1	-	1	-	-	1	14
Total	45	30	35	12	-	10	08	
		77			18			95

Rajiv Gandhi University of Health Sciences, Karnataka
FIFTH SEMESTER B.PHARM DEGREE EXAMINATION- DEC-2019

Time: Three Hours

Max.Marks:75 Marks

PHARMACOLOGY-II

Q.P. CODE: BP503T

Your answers should be specific to the questions asked

Draw neat labelled diagram wherever necessary

Long Essay (Answer any Two)

2X 10 = 20 Marks

1	Classify antihypertensive drugs with examples. Describe the pharmacology of Calcium channel blockers.
2	Describe the general methods of bioassay and explain the bioassay of d-Tubocurarine.
3	Classify Non-steroidal anti-inflammatory agents with examples. Write the mechanism and pharmacological actions of Aspirin.

Short Essays (Answer any Seven)

7x 5 = 35 Marks

4	Write the pharmacology of Quinidine.
5	Describe the mechanism of action and adverse effects of Furosemide.
6	Describe the pharmacological actions of Histamine.
7	Classify oral hypoglycemic agents with examples.
8	Write the pharmacology of corticosteroids.
9	Describe the mechanism action of action and adverse effects of oral contraceptives.
10	Describe the pharmacology of Heparin.
11	Explain the pharmacology of Prostaglandins.
12	Write the Pharmacology of Propyl thiouracil.

Short Answers (Answer any All)

10X2 = 20 Marks

13	Write the mechanism of action of Digoxin.
14	Enlist the oral anti coagulants.
15	Name different types of 5HT receptors and their antagonists.
16	Mode of action of Glucagon.
17	Write the therapeutic uses Oxytocin.
18	Mode of action of anti diuretic hormone.
19	Name the drugs used in the treatment of shock.
20	Mention the different types of insulin preparations.
21	Mode of action of Streptokinase
22	Classify anti rheumatic drugs with examples.

5th Semester of B. Pharma (PHARMACOGNOSY AND PHYTOCHEMISTRY-II THEORY – 45 HOURS)

1. Content distribution as per the list of topics, time allotted for each topic, distribution for ‘Must know’, ‘Desirable to know’ and ‘Nice to know’ and the probable weightage. The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Unit	Topic	Hours	Learning content distribution			Wt'age (Marks)
			Must know	Desirable to know	Nice to know	
1	General introduction, composition, chemistry and chemical classes, general methods of extraction and analysis, bio sources, therapeutic uses and commercial applications of following secondary metabolites.	14	Pharmacognostic studies of (BS, Morphology, Microscopy, Chemical constituents, Chemical tests, Uses, Adulterants and substitutes) : Alkaloids: Vinca, Rauwolfia, Belladonna, Opium. Glycosides: Senna. Aloes, Cardiac glycosides and steroids: Liquorice, Dioscorea, Digitalis. Terpenoids and Naphthaquinones: Taxus Buccata	Resins: Benzoin, Myrrh Colophony. Terpenoids and Naphthaquinones: Gentian, Phenyl propanoids and Flavonoids : Lignans, Tea and Ruta Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander.	Iridoids-Artemisia and Carotenoids. Bitter almond Tannins: Catechu, Pterocarpus. Resins: Guggul, Ginger, Asafoetida,	25

2.	Basics of Phytochemistry.	08	Modern methods of extraction: SFE, Microwave assisted Extraction and Solid phase Extraction (SPE)	Applications of Electrophoresis and chromatography (TLC, HPTLC and GC) in the isolation, purification and identification of crude drugs.	Applications of Spectroscopy	15
3	Isolation, identification and analysis of phytoconstituents	06	a) Glycosides: Glycyrrhetic acid b) Alkaloids: Quinine, Reserpine, c) Resins: Podophyllotoxin and Curcumin	a) Artemesin b) Rutin c) Atropine,	a) Menthol and Citral b) Caffeine,	10
4.	Metabolic pathways in higher plants and their determination	07	Brief study of basic metabolic pathways and formation of different secondary metabolites through Shikimic acid pathway. Study of utilization of radioactive isotopes in the investigation of Biogenetic studies -Tracer technique	Acetate pathways.	Amino acid pathways	10
5.	Industrial production, estimation and utilization of the Phytoconstituents	10	Industrial production, estimation and uses of the following Phytoconstituents: Sennoside, Diosgenin, Caffeine, Atropine, Forskolin	Digoxin, Artemisinin, Vincristine and vinblastine	Podophyllotoxin, and Taxol	15

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SEMESTER-V

(BP505T) PHARMACEUTICAL JURISPRUDENCE (Theory)

Unit No	Topic	Hours	Learning content distribution			Weightage (Marks)
			Must know	Desirable to know	Nice to know	
1.	Drugs and Cosmetics Act, 1940 and its rules 1945	10	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.	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.	Recent Updates On Fines And Penalties	10, 5, 2
2.	Drugs and Cosmetics Act, 1940 and its rules	10	Detailed study of Schedule : Schedule H, M, N, Y	Detailed study of Schedule	Schedule A, C, C1, H1, J and their	10, 5, 2

	1945		<p>Administration of the Act and Rules – Drugs Technical Advisory Board(DTAB), Central drugs Laboratory(CDL), Drugs Consultative Committee(DCC), Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors</p> <p>Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties</p>	<p>Schedule G, P,T,U, V, X, Part XII B Sch. F</p> <p>Labeling & Packing of drugs-</p> <p>General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.</p>	<p>applications, DMR (OA)</p>	
3.	Pharmacy Act – 1948	04	<p>Pharmacy Council of India; its constitution and functions, Education Regulations(ER), State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists.</p>	<p>Objectives, Definitions, Offences and Penalties</p>	<p>Recent Updates On Pharmacy Council of India</p>	10, 5, 2
	Medicinal and Toilet Preparation Act(M&TP) –1955	03	<p>Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.</p>	<p>Objectives, Definitions Offences and Penalties.</p>	<p>Recent Updates On Fines And Penalties</p>	5, 2

	Narcotic Drugs and Psychotropic substances Act(NDPS)-1985 and Rules	03	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,	Objectives, Definitions, Authorities and Officers, Offences and Penalties	Recent Updates NDPS Act-1985 and Rules	10, 5, 2
	Study of Salient Features of Drugs and Magic Remedies Act-(DMR)1955 and its rules	03	Prohibition of certain advertisements, Classes of Exempted advertisements	Objectives, Definitions Offences and Penalties		5, 2
4.	Prevention of Cruelty to Animals Act-1960	02	Institutional Animal Ethics committee (IAEC), 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,	Objectives, Definitions, Offences and Penalties		5, 2
	National Pharmaceutical Pricing Authority(NPPA)	03	Drugs Price Control Order (DPCO)-2013. Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations,	Objectives, Definitions, National List of Essential Medicines (NLEM)	Formula for calculating MRP of formulations	5, 2

5.	Pharmaceutical Legislations	02	A brief review, Introduction, Study of Drugs Enquiry Committee(DEC – Chopra Committee), Health survey and development committee,	Hathi committee and Mudaliar committee		5, 2
	Code of Pharmaceutical ethics	02	Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath		Objectives of code of Pharmaceutical ethics	5, 2
	Medical Termination of Pregnancy Act-1971(MTP)		Objectives, Procedure of Medical Termination of Pregnancies	Offences and Penalties		5, 2
	Right to Information Act(RTI)	01		Introduction and definitions, Responsibility of RTI		2
	Introduction to Intellectual Property Rights (IPR)	01		Definition of patent, Types of patents, Definition of Copyright, Trade secrets, Trade marks Act.		2

2. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

Sl.No.	Chapter	Marks distribution				Total Marks	
		Must Know	Desirable to Know	Long Essay	Short Essay		Short Answer
1.	Drugs and Cosmetics Act, 1940 and its rules 1945	<p>Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,</p> <p>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.</p>	<p>Objectives, Definitions, Legal definitions of schedules to the Act and Rules</p> <p>Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.</p>	10	05	02	22
2.	Drugs and Cosmetics Act, 1940 and its rules 1945	<p>Detailed study of Schedule : Schedule H, M, N, Y</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board(DTAB), Central drugs Laboratory(CDL), Drugs Consultative</p>	<p>Detailed study of Schedule Schedule G, P,T,U, V, X, Part XII B Sch. F</p> <p>Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted</p>	10	05	02	23

		Committee(DCC), Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties	colors. Offences and penalties.				
3.	Pharmacy Act –1948	Pharmacy Council of India; its constitution and functions, Education Regulations(ER), State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists.	Objectives, Definitions, Offences and Penalties	10	05	02	25
	Medicinal and Toilet Preparation Act(M&TP) –1955	Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.	Objectives, Definitions Offences and Penalties.				
	Narcotic Drugs and Psychotropic substances Act(NDPS)-1985 and	Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling	Objectives, Definitions, Authorities and Officers, Offences and Penalties				

	Rules	the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium,					
4.	Study of Salient Features of Drugs and Magic Remedies Act-(DMR)1955 and its rules	Prohibition of certain advertisements, Classes of Exempted advertisements	Objectives, Definitions Offences and Penalties		05	02	15
	Prevention of Cruelty to Animals Act-1960	Institutional Animal Ethics Committee(IAEC), 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,	Objectives, Definitions, Offences and Penalties		05	02	
	National Pharmaceutical Pricing Authority(NPPA)	Drugs Price Control Order (DPCO)-2013. Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled	Objectives, Definitions, National List of Essential Medicines (NLEM)		05	02	

		formulations,					
5.	Pharmaceutical Legislations	A brief review, Introduction, Study of Drugs Enquiry Committee(DEC – Chopra Committee), Health survey and development committee,	Hathi committee and Mudaliar committee		05	02	15
	Code of Pharmaceutical ethics	Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath			05	02	
	Medical Termination of Pregnancy Act-1971(MTP)	Objectives, Procedure of Medical Termination of Pregnancies	Offences and Penalties			02	
	Right to Information Act(RTI)		Introduction and definitions, Responsibility of RTI			02	
	Introduction to Intellectual Property Rights (IPR)		Definition of patent, Types of patents, Definition of Copyright, Trade secrets, Trade marks Act.			02	
Total							100

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to Know area of the Curriculum.

3. Question paper layout to show which question number will represent which chapter (s)

BP505 T PHARMACEUTICAL JURISPRUDENCE
V – SEMESTER B- PHARM

Maximum Marks: 75

Long Essay: Answer any Two 2X 10 = 20

1	Describe the conditions for grant of licence and conditions for manufacturing of drugs, examinations and analysis.
2	Explain in detail about grant of licence for whole sale, retail sale and restricted licence.
3	Write the constitution and functions of Pharmacy Council of India (PCI). Explain in brief about education regulations with salient features ER -91.

Short Essays: Answer any Nine 9 x 5 = 45

4	What is drug enquiry committee (DEC)? Mention the recommendations of DEC.
5	Describe the role of pharmacists in relation to his job.
6	Write a note on first and subsequent registers.
7	Explain about the requirements of the bonded laboratory as per M & T P Act
8	Explain in detail about opium poppy cultivation and production of poppy straw.
9	Write the specimen label for schedule “H” drug with example.
10	Mention the qualification and duties of drugs inspector.
11	Write the constitution and functions of drugs technical advisory board (DTAB).
12	Describe the classes of prohibited advertisements under DMR act.
13	Explain in detail about schedule “N”.

Short Answers: (Answer All Questions) 5X2 = 10

14	Define the term misbranded drug as per D&C act.
15	Add a note on loan licence.
16	Define the term patent.
17	What is Hathi committee?
18	Write the offences and penalties in contravention of NDPS act.

4. Scheme of Practical / Clinical Teaching and Assessment:

List the expected practical / clinical competencies.

State the objectives for each competencies.

Assign content for the objectives.

Describe the teaching – learning process.

Sl No	Skills	Duration	Learning methods
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Scheme of examination with the distribution of marks as per the prioritisation of competencies.

Sl No	Competency	Assessment criteria	Marks
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5. Suggested references (as per APA style):

- Basic references
- Advanced references (may also include journals / web / other electronic sources)