

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

**GOVERNMENT OF KARNATAKA
(BOARD OF EXAMINING AUTHORITY)**

**D Pharm Part –II Examination (ER 2020)- Month- Year
PHARMACOLOGY-610**

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks
35. Match the following
 - 1.
 - 2.
 - 3.
 - 4.

- A.
- B.
- C.
- D.
- E.
- F.

Subject Experts: Name and Signature

1. Shri Harisha R

Dr Nirmala P

2. Dr Bheemachar

Dr Vijaya G Joshi

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

**GOVERNMENT OF KARNATAKA
(BOARD OF EXAMINING AUTHORITY)**

**D Pharm Part –II Examination (ER 2020)- Month- Year
COMMUNITY PHARMACY AND MANAGEMENT -620**

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks
35. Match the following

- | | |
|----|----|
| 1. | A. |
| 2. | B. |
| 3. | C. |
| 4. | D. |
| | E. |
| | F. |

Subject Experts: Name and Signature

1. Dr Bheemachar

Dr Nirmala P

Dr Vijaya G Joshi

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

**GOVERNMENT OF KARNATAKA
(BOARD OF EXAMINING AUTHORITY)**

**D Pharm Part –II Examination (ER 2020)- Month- Year
BIOCHEMISTRY AND CLINICAL PATHOLOGY -630**

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks
35. Match the following

- | | |
|----|----|
| 1. | A. |
| 2. | B. |
| 3. | C. |
| 4. | D. |
| | E. |
| | F. |

Subject Experts: Name and Signature

1. Dr Zaranappa

Dr Nirmala P

2. Mrs Anupama R

Dr Vijaya G Joshi

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

**GOVERNMENT OF KARNATAKA
(BOARD OF EXAMINING AUTHORITY)**

D Pharm Part –II Examination (ER 2020)- Month- Year

PHARMACOTHERAPEUTICS - 640

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks

35. Match the following

- | | |
|----|----|
| 1. | A. |
| 2. | B. |
| 3. | C. |
| 4. | D. |
| | E. |
| | F. |

Subject Experts: Name and Signature

1. Dr M S Rajesh

Dr Nirmala P

2. Dr. T Vithya

Dr Vijaya G Joshi

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

GOVERNMENT OF KARNATAKA

(BOARD OF EXAMINING AUTHORITY)

D Pharm Part –II Examination (ER 2020)- Month- Year

HOSPITAL AND CLINICAL PHARMACY -650

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks
35. Match the following
 - 1.
 - 2.
 - 3.
 - 4.

- A.
- B.
- C.
- D.
- E.
- F.

Subject Experts: Name and Signature

1. Mrs Deepali

Dr Nirmala P

2. Dr. T Vithya

Dr Vijaya G Joshi

Sub Code

QUESTION PAPER TEMPLATE FOR D PHARM PART –II (ER2020)

**GOVERNMENT OF KARNATAKA
(BOARD OF EXAMINING AUTHORITY)**

**D Pharm Part –II Examination (ER 2020)- Month- Year
PHARMACY LAW AND ETHICS -660**

Time : 03 Hours

Max Marks: 80Marks

Long Essay (Answer any six)

6Q x5M =30Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

Short Essay (Answer any ten)

10Q x 3M = 30Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

Objective type (Answer all questions)

20Q x 1M = 20Marks

- 19.
- 20.
- 21.
- 22.
- 23.
- 24.
- 25.
- 26.
- 27.
- 28.
- 29.
- 30.
31. Fill in the blanks
32. Fill in the blanks
33. Fill in the blanks
34. Fill in the blanks
35. Match the following
 - 1.
 - 2.
 - 3.
 - 4.

- A.
- B.
- C.
- D.
- E.
- F.

Subject Experts: Name and Signature

1. Mrs Manjula B P

Dr Nirmala P

2. Dr. M Geetha

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020
SUBJECT: 610 -PHARMACOLOGY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

Topic no.	Name of the topic	Total weightage in marks	No. Of 1 mark questions	No. Of 3 mark questions	No. Of 5 mark questions
1	General pharmacology	3+3+5=11	3	1	1
2	Drugs acting on peripheral nervous system	3+3+5=11	3	1	1
3	Drugs acting on eye	2+0+0=2	2	-	-
4	Drugs acting on central nervous system	3+3+5=11	3	1	1
5	Drugs acting on cardiovascular system	0+3+5=8	-	1	1
6	Drugs acting on blood and blood forming organs	2+3+0=5	2	1	-
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> • Bronchodilators • Expectorants • Anti-tussive agents • Mucolytic agents 	0+3+0=3	-	1	-
8	Drugs Acting on the Gastro Intestinal Tract	2+1+0=5	2	1	-
9	Drugs Acting on the Kidney	1+3+0=4	1	1	-
10	Hormones and Hormone Antagonists	1+3+5=9	1	1	1
11	Autocoids	1+3+0=4	1	1	-
12	Chemotherapeutic Agents	0+3+10=13	-	1	2
13	Biologicals	2+0+0=2	2	-	-

Subject Experts: Name and Signature

1 . Shri Harisha R

Dr Nirmala P

BLUEPRINT FOR D PHARM PART II ER 2020
SUBJECT: 610 -PHARMACOLOGY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

2. Dr Bheemachar

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020**SUBJECT: 620 –COMMUNITY PHARMACY AND MANAGEMENT - TOPIC WISE MARKS AND QUESTION WEIGHTAGE**

TOPIC NO.	NAME OF THE TOPIC	TOTAL WEIGHTAGE IN MARKS	NO. OF 1 MARK QUESTIONS	NO. OF 3 MARK QUESTIONS	NO. OF 5 MARK QUESTIONS
1	Community Pharmacy Practice	1+3+0=4	1	1	--
2	Professional responsibilities of community pharmacists	2+3+0=5	2	1	--
3	Prescription and prescription handling	2+3+5=10	2	1	1
4	Communication skills	2+3+0=5	2	1	--
5	Patient counseling	2+3+5=10	2	1	1
6	Medication Adherence	3+0+0=3	3	--	--
7	Health Screening Services in Community Pharmacy	3+3+0=6	3	1	--
8	Over The Counter (OTC) Medications	3+6+10=19	3	2	2
9	Community Pharmacy Management	2+9+15=26	2	3	3

Subject expert: Dr Bheemachar

Dr Nirmala P

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 630 - BIOCHEMISTRY AND CLINICAL PATHOLOGY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

Chapter no	Name of the chapter	Total weightage in marks	No. Of questions (1M)	No. Of questions (3M)	No. Of questions (5M)
1	Introduction to biochemistry: Scope of biochemistry in pharmacy; cell and its biochemical organization.	1+0+0 = 01	1	0	0
2.	Carbohydrates <ul style="list-style-type: none"> • Definition, classification with examples, chemical properties • Monosaccharides- Structure of glucose, fructose, and galactose • Disaccharides – structure of maltose, lactose, and sucrose • Polysaccharides – chemical nature of starch and glycogen • Qualitative tests and biological role of carbohydrates 	1+3+5 = 09	1	1	1
3.	Proteins <ul style="list-style-type: none"> • Definition, classification of proteins based on composition and solubility with examples • Definition, classification of amino acids based on chemical nature and nutritional requirements with examples • Structure of proteins (four levels of organization of protein structure) • Qualitative tests and biological role of proteins and amino acids • Diseases related to malnutrition of proteins 	1+3+5 = 09	1	1	1
4.	Lipids <ul style="list-style-type: none"> • Definition, classification with examples • Structure and properties of triglycerides (oils and fats) • Fatty acid classification-based on chemical and nutritional requirements with examples • Structure and functions of cholesterol in the body • Lipoproteins-types, composition and functions of lipids 	1+0+5 = 06	1	0	1

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 630 - BIOCHEMISTRY AND CLINICAL PATHOLOGY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

5.	<p>Nucleic acids</p> <ul style="list-style-type: none"> • Definition, purine and pyrimidine bases • Components of nucleosides and nucleotides with examples • Structure of DNA (Watson and crick model), RNA and their functions 	1+3+0 = 04	1	1	0
6.	<p>Enzymes</p> <ul style="list-style-type: none"> • Definition, properties and IUB and MB classification • Factors affecting enzyme activity • Mechanism of action of enzymes, Enzyme inhibitors • Therapeutic and pharmaceutical importance of enzymes 	2+3+5 = 10	2	1	1
7.	<p>Vitamins</p> <ul style="list-style-type: none"> • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form recommended dietary requirements, deficiency diseases of fat- and water-soluble vitamins 	2+3+5 = 10	2	1	1
8.	<p>Metabolism (study of cycle/pathways without chemical structures)</p> <ul style="list-style-type: none"> • Metabolism of carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose level, diseases related to abnormal metabolism of carbohydrates • Metabolism of lipids: Lipolysis, β-oxidation of fatty acid (palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as ketoacidosis, fatty liver, Hypercholesterolemia • Metabolism of amino acids (proteins): General reactions of amino acids its significance Transamination, Deamination, Urea cycle and decarboxylation, deamination, urea cycle and decarboxylation, diseases related to abnormal metabolism of amino acids, disorders of ammonia metabolism, phenylketonuria, alkaptonuria and jaundice • Biological oxidation; Electron transport chain and oxidative phosphorylation 	5+6+10 = 21	5	2	2

BLUEPRINT FOR D PHARM PART II ER 2020**SUBJECT: 630 - BIOCHEMISTRY AND CLINICAL PATHOLOGY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE**

9.	Minerals: Types, Functions, Deficiency diseases, recommended dietary requirements	2+3+0 = 05	2	1	0
10.	Water and Electrolytes <ul style="list-style-type: none">• Distribution, functions of water in the body• Water turnover and balance• Electrolyte composition of the body fluids, dietary intake of electrolyte and electrolyte balance• Dehydration, causes of dehydration and oral rehydration therapy	1+3+0 = 04	1	1	0
11.	Introduction to Biotechnology	1 +0+0 = 01	1	0	0
12.	Organ function tests <ul style="list-style-type: none">• Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances• Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances• Lipid profile tests and its clinical significances	1+3+0 = 04	1	1	0
13	Introduction to Pathology of Blood and Urine <ul style="list-style-type: none">• Lymphocytes and platelets, their role in health and disease• Erythrocytes-Abnormal cells and their significance• Normal and Abnormal constituents of urine and their significance	1+3+0 = 04	1	1	0
	Total				

Subject Experts: Name and Signature

1. Dr. Zaranappa

Dr Nirmala P

2. Smt. Anupama R

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020
SUBJECT: 640 - PHARMACOTHERAPEUTICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

CHAPTER NO	NAME OF THE CHAPTER	TOTAL WEIGHTAGE IN MARKS	NO. OF QUESTION (1M)	NO. OF QUESTIONS (3M)	NO. OF QUESTIONS (5M)
1	Pharmacotherapeutics- Introduction, scope and objectives. Rational use of medicines, Evidence based medicine list, Standard Treatment Guidelines (STGs)	1+3=4	1	1	0
2.	Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of the diseases associated with				
	(a) Cardiovascular System <ul style="list-style-type: none"> • Hypertension • Angina and Myocardial infarction • Hyperlipidaemia • Congestive Heart Failure 	1+6+5=12	1	2	1
	(b) Respiratory System <ul style="list-style-type: none"> • Asthma • COPD 	1+3=4	1	1	0
	(c) Endocrine System <ul style="list-style-type: none"> • Diabetes • Thyroid disorders - Hypo and Hyperthyroidism 	1+3+5=9	1	1	1
	(d) Central Nervous System <ul style="list-style-type: none"> • Epilepsy • Parkinson's disease • Alzheimer's disease • Stroke • Migraine 	1+3+10=14	1	1	2
	(e) Gastro Intestinal Disorders <ul style="list-style-type: none"> • Gastro oesophageal reflux disease 				

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 640 - PHARMACOTHERAPEUTICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	<ul style="list-style-type: none"> • Peptic Ulcer Disease • Alcoholic liver disease • Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis) 	1+3+5=9	1	1	1
	(f) Haematological disorders <ul style="list-style-type: none"> • Iron deficiency anaemia • Megaloblastic anaemia 	1+3=4	1	1	0
	(g) Infectious diseases <ul style="list-style-type: none"> • Tuberculosis • Pneumonia • Urinary tract infections • Hepatitis • Gonorrhoea and Syphilis • Malaria • HIV and Opportunistic infection • Viral Infections (SARS, CoV2) 	2+3+10=15	2	1	2
	(h) Musculoskeletal disorders <ul style="list-style-type: none"> • Rheumatoid arthritis • Osteoarthritis 	2+3=5	2	1	0
	(i) Dermatology <ul style="list-style-type: none"> • Psoriasis • Scabies • Eczema 	2	2	0	0
	(j) Psychiatric Disorders <ul style="list-style-type: none"> • Depression • Anxiety 	2+3=5	2	1	0

BLUEPRINT FOR D PHARM PART II ER 2020
SUBJECT: 640 - PHARMACOTHERAPEUTICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	<ul style="list-style-type: none"> • Psychosis 				
	(k) Ophthalmology <ul style="list-style-type: none"> • Conjunctivitis (bacterial and viral) • Glaucoma 	1	1	0	0
	(l) Anti-microbial Resistance	1	1	0	0
	(m) Women's Health <ul style="list-style-type: none"> • Polycystic Ovary Syndrome • Dysmenorrhea • Premenstrual Syndrome 	3	3	0	0
	TOTAL MARKS	88	20	11	7

Subject Experts: Name and Signature

1 . Dr MS Rajesh

Dr Nirmala P

2. Dr Vithya T

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 650 - HOSPITAL AND CLINICAL PHARMACY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

Chapter no	Name of the chapter	Total weightage in marks	No. Of questions (1M)	No. Of questions (3M)	No. Of questions (5M)
1	Hospital Pharmacy Definition, scope, National and international scenario Organisational structure Professional responsibilities, Qualification and experience Requirements, job specifications, work load requirements and inter professional relationships Good Pharmacy Practice (GPP) in hospital Hospital Pharmacy Standards (FIP Basel Statements, AHSP) Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	1+3=4	1	1	0
2.	Different Committees in the Hospital Pharmacy and Therapeutics Committee - Objectives, Composition, and functions Hospital Formulary - Definition, procedure for development and use of hospital formulary Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance	1+3+5=9	1	1	1
3.	Supply Chain and Inventory Control Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics Procedures of Drug Purchases – Drug selection, short term, long term, and tender/e-tender process, quotations, etc. Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc. Inventory Management of Central Drug Store – Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator,	2+3+10=15	2	1	2

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 650 - HOSPITAL AND CLINICAL PHARMACY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	ILR, Walk-in-Cold rooms) FEFO, FIFO methods Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs Documentation - purchase and inventory				
4.	Drug distribution Drug distribution (in- patients and out - patients) –Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method. Distribution of drugs to ICCU/ICU/NICU/Emergency wards. Automated drug dispensing systems and devices Distribution of Narcotic and Psychotropic substances and their storage	1+3+5=9	1	1	1
5.	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	2+3=5	2	1	0
6.	Radio Pharmaceuticals - Storage, dispensing and disposal of radiopharmaceuticals	1	1	0	0
7.	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy	2+3=5	2	1	0
8.	Clinical Pharmacy: Definition, scope, and development – in India and other countries Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc. Daily activities of clinical pharmacists: Definition, goal, and procedure of Ward round participation Treatment Chart Review Adverse drug reaction monitoring Drug information and poisons information Medication history Patient counselling	2+6+10=18	2	2	2

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 650 - HOSPITAL AND CLINICAL PHARMACY - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	Interprofessional collaboration Pharmaceutical care: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care Medication Therapy Management, Home Medication Review				
9.	Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results Haematological, Liver function, Renal function, thyroid function tests Tests associated with cardiac disorders Fluid and electrolyte balance Pulmonary Function Tests	3+3+5=11	3	1	1
10.	Poisoning: Types of poisoning: Clinical manifestations and Antidotes Drugs and Poison Information Centre and their services – Definition, Requirements, Information resources with examples, and their advantages and disadvantages.	1+3=4	1	1	0
11.	Pharmacovigilance Definition, aim and scope Overview of Pharmacovigilance	2	2	0	0
12.	Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP Drug Interactions: Definition, types, clinical significance of drug interactions	2+3=5	2	1	0
	Total	88	20	11	7

Subject Experts: Name and Signature

1. Mrs Deepali

Dr Nirmala P

2. Dr. T Vithya

Dr Vijaya G Joshi

BLUEPRINT FOR D PHARM PART II ER 2020**SUBJECT: 660 - PHARMACY LAW AND ETHICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE**

Sl No.	Name of the topic	Total weightage in marks	No. of 1 mark questions	No. of 3 marks questions	No. of 5 marks questions
1.	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2	2	-	-
2.	Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015	3+5=8	-	1	1
3.	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 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 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. Study of schedule C and C1, G, H, H1, K,	1+6+10=17	1	2	2

BLUEPRINT FOR D PHARM PART II ER 2020**SUBJECT: 660 - PHARMACY LAW AND ETHICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE**

	<p>P, M, N, and X.</p> <p>Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy. Drugs Prohibited for manufacture and sale in India.</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.</p>				
4.	<p>Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.</p>	1+3=4	1	1	-
5.	<p>Drugs and Magic Remedies (Objectionable Advertisements) Act 1954. Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.</p>	1+3=4	1	1	-
6.	<p>Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and</p>	1+3=4	1	1	-

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 660 - PHARMACY LAW AND ETHICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	Penalties.				
7.	Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	3	-	1	-
8.	FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	1	1	-	-
9.	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, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	2+3+5=10	2	1	1
10.	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath	5	-	-	1
11.	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	3	-	1	-
12.	Role of all the government pharma regulator bodies –Central Drugs Standards Control Organization (CDSCO), Indian	3	-	1	-

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 660 - PHARMACY LAW AND ETHICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	Pharmacopoeia Commission (IPC)				
13.	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices.	1+3+5=9	1	1	1
14.	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	1+5=6	1	-	1
15.	Blood bank – basic requirements and functions	2	2	-	-
16.	Clinical Establishment Act and Rules – Aspects related to Pharmacy	1	1	-	-
17.	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	2	2	-	-
18.	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical	1	1	-	-

BLUEPRINT FOR D PHARM PART II ER 2020

SUBJECT: 660 - PHARMACY LAW AND ETHICS - TOPIC WISE MARKS AND QUESTION WEIGHTAGE

	and Health Research involving human participants				
19.	Introduction to the Consumer Protection Act	1	1	-	-
20.	Introduction to the Disaster Management Act	1	1	-	-
21.	Medical Devices – Categorization, basic aspects related to manufacture and sale.	1	1	-	-

Subject Experts: Name and Signature

1. Mrs Manjula B P

Dr Nirmala P

2. Dr. M Geetha

Dr Vijaya G Joshi