

**GUJARAT TECHNOLOGICAL UNIVERSITY**

PHARM.D

3<sup>rd</sup> Year

**Subject Name: Pharmacology-II**

**Subject Code: 838801**

**Scope:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on blood and blood forming agents, renal system, chemotherapy, immune system, animal toxicology, cell structure and functions, genome structure and functions and biotechnology methods will be concentrated. Pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

**Objectives:**

- a) understand the pharmacological aspects of drugs falling under the above mentioned chapters
- b) carry out the animal experiments confidently
- c) appreciate the importance of pharmacology subject as a basis of therapeutics, and
- d) correlate and apply the knowledge therapeutically

**Theory (3 Hours/ Week, Total: 90 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr.	Topic	Hr	% Weightage
1.	<b>Pharmacology of Drugs acting on Blood and blood forming agents</b> a) Anticoagulants b) Thrombolytics and antiplatelet agents c) Haemopoietics and plasma expanders	8	8.88%
2.	<b>Pharmacology of drugs acting on Renal System</b> a) Diuretics b) Antidiuretics	7	7.77%
3.	<b>Chemotherapy</b> a) Introduction b) Sulfonamides and co-trimoxazole c) Penicillins and Cephalosporins d) Tetracyclins and Chloramphenicol e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics f) Quinolines and Fluroquinolines g) Antifungal antibiotics h) Antiviral agents i) Chemotherapy of tuberculosis and leprosy j) Chemotherapy of Malaria k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis) l) Pharmacology of Anthelmintic drugs m) Chemotherapy of cancer (Neoplasms)	30	33.3 %
4.	<b>Immunopharmacology</b> Pharmacology of immunosuppressants and stimulants	4	4.4%
5.	<b>Principles of Animal toxicology</b> Acute, sub acute and chronic toxicity	6	6.7%
6.	<b>The dynamic cell: The structures and functions of the components of the cell</b> a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies b) Chromosome structure: Pro and eukaryotic chromosome structures,	15	16.7%

	chromatin structure, genome complexity, the flow of genetic information. c) DNA replication: General, bacterial and eukaryotic DNA replication. d) The cell cycle: Restriction point, cell cycle regulators and modifiers. e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).		
7.	<b>The Gene: Genome structure and function:</b> a) Gene structure: Organization and elucidation of genetic code. b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families). c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.	10	11.1%
8.	RNA processing: rRNA, tRNA and mRNA processing. Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes. The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting. Recombinant DNA technology: principles. Processes (gene transfer technology) and applications	10	11.1%

#### Text books (Theory)

- Tripathi, K. D. Essentials of medical pharmacology. Latest Edition. Publisher: Jaypee, Delhi.
- Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. Latest Edition. Publisher: Popular, Dubai.
- Rang, H.P. and Dale, M.M. Pharmacology. Latest Edition. Publisher: Churchill Livingstone
- Gerald K., Janet I. and Wallace M. Cell and Molecular Biology: Concepts and Experiments by Latest Edition. Publisher: Wiley

#### Reference books (Theory)

- Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's. The pharmacological Basis of therapeutics. Latest Edition. Publisher: Mc Graw Hill, Pergamon press.
- Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B. V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.
- Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD. Molecular Biology of the Cell, Latest edition. Publisher: W W Norton and Company.
- Lodish, H., Baltimore, D., Berk, A et al.,Molecular Cell Biology Latest edition. Publisher: W H freeman and Company Ltd.
- Turner, PC., McLennan, AG., Bates, AD and White MRH. Instant notes in molecular Biology. Latest edition. Publisher: Bios scientific publisher, Oxford
- Lewin, B . Genes XII ., (2018) Publishers: Jones and Bartlett Publishers Inc.
- Crommelin, DJA and Sindelar RD. Pharmaceutical Biotechnology. Latest Edition. Publisher Springer.
- Watson, JD., Gilman, M., et al. Recombinant DNA Latest Edition. Publisher: W H Freeman.
- Walsh, G Biopharmaceutical: Biochemistry and Biotechnology., Latest Edition. Publisher: Wiley.

#### Text books (Practical)

- Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallabh, Delh

**Reference books (Practical):**

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

**List of Experiments:**

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments: a) Analgesic property of drug using analgesiometer. b) Antiinflammatory effect of drugs using rat-paw edema method. c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods. d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods. e) Locomotor activity evaluation of drugs using actophotometer and rotorod. f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

**Scheme of Practical Examination:**

	Sessional	Annuals
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>3hrs</b>	<b>4hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
3<sup>rd</sup> Year

**Subject Name: PHARMACEUTICAL ANALYSIS**  
**Subject Code: 838802**

**Scope:** This subject will delve upon concepts of quality assurance, various analytical methods used for pharmaceutical formulations.

**Objectives:**

- a. To study quality assurance concepts, validation methods, ICH guidelines, GLP
- b. To study various chromatographic techniques.
- c. To study electrometric methods and spectroscopy methods.

**Theory (3 Hours/ Week, Total: 90 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr.	Topic	Hr	% Weigh tage
<b>1.</b>	<p><b>Quality Assurance:</b> a. Introduction, sources of quality variation, control of quality variation. b. Concept of statistical quality control. c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration. d. GLP, ISO 9000. e. Total quality management, quality review and documentation. f. ICH- international conference for harmonization-guidelines. g. Regulatory control.</p>	<b>10</b>	<b>11.1%</b>
<b>2.</b>	<p><b>Chromatography:</b> Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.</p> <p>a. <b>Column Chromatography:</b> Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.</p> <p>b. <b>TLC:</b> Introduction, principle, techniques, Rf value and applications.</p> <p>c. <b>PC:</b> Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.</p> <p>d. <b>Ion-exchange chromatography:</b> Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.</p> <p>e. <b>HPLC:</b> Introduction, theory, instrumentation, and applications.</p> <p>f. <b>HPTLC:</b> Introduction, theory, instrumentation, and applications.</p> <p>g. <b>Gas Chromatography:</b> Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC &amp; GSC. Detectors-Flame ionization detectors,</p>	<b>30</b>	<b>33.3%</b>

	<p>electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.</p> <p>h. <b>Electrophoresis:</b> Principles of separation, equipment for paper and gel electrophoresis, and application.</p> <p>i. <b>Gel filtration and affinity chromatography:</b> Introduction, technique, applications.</p>		
3.	<p><b>Electrometric Methods:</b> Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.</p> <p>a. <b>Potentiometry:</b> Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.</p> <p>b. <b>Conductometry:</b> Introduction, conductivity cell, conductometric titrations and applications.</p> <p>c. <b>Polarography:</b> Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.</p> <p>d. <b>Amperometric Titrations:</b> Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications</p>	15	16.7%
4.	<p><b>Spectroscopy:</b> Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:</p> <p>a. <b>Absorption Spectroscopy:</b> - Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.</p> <p><b>Instrumentation</b> – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.</p> <p>- <b>Infrared Spectroscopy:</b> Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors–Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.</p> <p>- <b>Fluorimetric Analysis:</b> Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry</p> <p>b. <b>Flame Photometry:</b> Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.</p> <p>c. <b>Atomic Absorption Spectrometry:</b> Introduction, Theory, types of electrodes, instrumentation and applications.</p> <p>d. <b>Atomic Emission Spectroscopy:</b> Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.</p>	35	38.9%

	<p>e. <b>NMR &amp; ESR (introduction only):</b> Introduction, theoretical aspects and applications.</p> <p>f. <b>Mass Spectroscopy: (Introduction only)</b> – Fragmentation, types of ions produced mass spectrum and applications.</p> <p>g. <b>Polarimetry: (Introduction only)</b> – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.</p> <p>h. <b>X-RAY Diffraction: (Introduction only)</b> – Theory, reciprocal lattice concept, diffraction patterns and applications.</p> <p>i. <b>Thermal Analysis:</b> Introduction, instrumentation, applications, and DSC and DTA.</p>		
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### **Practicals:**

#### **List of Experiments:**

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

#### **Reference Books:**

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York. Latest edition
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London. Latest edition
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers. Latest edition
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras. Latest edition
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing. Latest edition
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire. Latest edition
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore. Latest edition

9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi. Latest edition
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi. Latest edition
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore. Latest edition
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra. Latest edition
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania. Latest edition
14. TLC by Stahl, Spring Verlay. Latest edition
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications. Latest edition
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire. Latest edition
17. I.P.-1996, The Controller of Publications, New Delhi. Latest edition
18. BPC- Dept. of Health, U.K. for HMSO. Latest edition
19. USP - Mack Publishing Co., Easton, PA. 20. The Extra Pharmacopoeia – The Pharm. Press, London Latest edition

**Scheme of Practical Examination:**

	Sessional	Annuals
Synopsis	05	10
Major Experiment	08	30
Minor Experiment	05	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>3hrs</b>	<b>4hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
 3<sup>rd</sup> Year

**Subject Name: PHARMACOTHERAPEUTICS – II**  
**Subject Code: 838803**

**Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Objectives:**

- a. know the pathophysiology of selected disease states and the rationale for drug therapy
- b. know the therapeutic approach to management of these diseases;
- c. know the controversies in drug therapy;
- d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
- e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

**Theory (3 Hours/ Week, Total: 90 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr.	Topic	Hr	% Weightage
1.	<b>Infectious disease:</b> Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis	35	38.9 %
2.	<b>Musculoskeletal disorders</b> Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus	10	11.1 %
3.	<b>Renal system</b> Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	10	11.1 %
4.	<b>Oncology:</b> Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	25	27.8 %
5.	<b>Dermatology:</b> Psoriasis, Scabies, Eczema, Impetigo	10	11.1 %

**Text books (Theory)**

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication, Latest Edition



**Reference books (Theory)**

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange, Latest Edition
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication, Latest Edition
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA], Latest Edition

**Practicals :** Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion. A minimum of 20 cases should be presented and recorded covering most common diseases.

**Assignments:** Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

**Format of the assignment:**

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

<b>Sessionals</b>		<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03 hrs</b>	<b>04 hrs</b>

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
**3<sup>rd</sup> Year**

**Subject Name: PHARMACEUTICAL JURISPRUDENCE**  
**Subject Code: 838804**

**Scope:** This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

**Objectives:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –

- a. practice the Professional ethics;
- b. understand the various concepts of the pharmaceutical legislation in India;
- c. know the various parameters in the Drug and Cosmetic Act and rules;
- d. know the Drug policy, DPCO, Patent and design act;
- e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
- g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

**Theory (2 Hours/ Week, Total: 60 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	0	0	2	70	30	0	0	100

Sr.	Topic	Hr	% Weig htag e
1.	<b>Pharmaceutical Legislations</b> – A brief review	3	5%
2.	Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI	3	5%
3.	<b>Drugs and Cosmetics Act, 1940, and its rules 1945.</b> Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties –Govt. analyst and Drugs Inspector	16	26.7%
4.	<b>Pharmacy Act –1948.</b> Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER	6	10%
5.	<b>Medicinal and Toilet Preparation Act –1955.</b> Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.	5	8.33%
6.	<b>Narcotic Drugs and Psychotropic substances Act-1985 and Rules.</b> Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic &	7	11.7%

	Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.		
7.	<b>Study of Salient Features of Drugs and magic remedies Act and its rules</b>	4	6.67%
8.	<b>Study of essential Commodities Act Relevant to drugs price control Order</b>	3	5%
9.	<b>Drug Price control Order &amp; National Drug Policy (Current).</b>	3	5%
10.	<b>Prevention Of Cruelty to animals Act-1960</b>	2	3.33%
11.	<b>Patents &amp; design Act-1970</b>	4	6.67%
12.	<b>Brief study of prescription and Non-prescription Products</b>	4	6.67%

### **Assignments:**

#### **Format of the assignment**

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

#### **Case studies relating to**

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

#### **Text books (Theory)**

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

#### **Reference books (Theory)**

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

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
**3<sup>rd</sup> Year**

**Subject Name: MEDICINAL CHEMISTRY**  
**Subject Code: 838805**

**Scope:** This subject will delve upon QSAR, computer aided drug design and synthesis of various anti-infective agents, antineoplastic agents and hormones and their antagonists.

**Objectives:**

- a. To study QSAR, CADD and structural activity relationships.
- b. To study synthesis of various anti-infective agents
- c. To study synthesis of various anticancer drugs.
- d. To study synthesis of drugs resembling hormones and antagonising their actions.

**Theory (3 Hours/ Week, Total: 90 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr.	Topic	Hr	% Weigh tage
1.	Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules. A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.	10	11.1%
2.	Anti-infective agents a) Local anti-infective agents b) Preservatives c) Antifungal agents d) Urinary tract anti-infectives e) Antitubercular agents f) Antiviral agents and Anti AIDS agents g) Antiprotozoal agents h) Anthelmentics i) Antiscabies and Antipedicular agents	10	11.1%
3.	Sulphonamides and sulphones	3	3.33%
4.	Antimalarials	4	4.44%
5.	Antibiotics	12	13.33%
6.	Antineoplastic agents	5	5.55%
7.	Cardiovascular agents a) Antihypertensive agents b) Antianginal agents and vasodilators c) Antiarrhythmic agents d) Antihyperlipidemic agents e) Coagulants and Anticoagulants f) Endocrine	16	17.8%
8.	Hypoglycemic agents	7	7.8%
9.	Thyroid and Antithyroid agents	4	4.44%
10.	Diuretias	5	5.55%
11.	Diagnostic agents	4	4.44%

<b>12.</b>	<b>Steroidal Hormones and Adrenocorticoids</b>	<b>10</b>	<b>11.1%</b>
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**Practical : 3 Hrs./Week** 1. Assays of important drugs from the course content.

2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

**Reference Books:**

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia. Latest Edition
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi. Latest Edition
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walfed Johnwilley and Sons, Wiley-interscience Publication, New York, Toronto. Latest Edition
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10. Latest Edition
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54. Latest Edition
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19. Latest Edition
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II. Latest Edition
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann. Latest Edition
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania. Latest Edition

**Scheme of Practical Examination:**

	Sessional	Annuals
Synopsis	05	10
Major Experiment	08	30
Minor Experiment	05	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>3hrs</b>	<b>4hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
**3<sup>rd</sup> Year**

**Subject Name: PHARMACEUTICAL FORMULATIONS**  
**Subject Code: 838806**

**Scope:** Subject deals with the formulation and evaluation of various pharmaceutical dosage forms

**Objectives:** Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. understand the principle involved in formulation of various pharmaceutical dosage forms;
- b. prepare various pharmaceutical formulation;
- c. perform evaluation of pharmaceutical dosage forms; and
- d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

**Theory (2 Hours/ Week, Total: 60 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	3	7	70	30	70	30	200

Sr.	Topic	Hr	% Weig htag e
1.	Pharmaceutical dosage form- concept and classification	3	5%
2.	<b>Tablets:</b> Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet	12	20%
3.	<b>Capsules;</b> Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules	8	13.3%
4.	<b>Liquid orals:</b> Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations	7	11.7%
5.	<b>Parenterals</b> Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization	12	20%
6.	<b>Ophthalmic preparations (Semi – Solids):</b> Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging	8	13.33 %
7.	Definition and concept of <b>Controlled and novel Drug delivery systems</b> with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular	10	11.1%

**Practicals:-****List of Experiments:**

- 1. Manufacture of Tablets** a. Ordinary compressed tablet-wet granulation b. Tablets prepared by direct compression. c. Soluble tablet. d. Chewable tablet.
- 2. Formulation and filling of hard gelatin capsules**
- 3. Manufacture of parenterals** a. Ascorbic acid injection b. Calcium gluconate injection c. Sodium chloride infusion. d. Dextrose and Sodium chloride injection/ infusion.
- 4. Evaluation of Pharmaceutical formulations (QC tests)** a. Tablets b. Capsules c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay** a. Solution: Paracetamol Syrup b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay** a. Salicylic acid and benzoic acid ointment b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations** a. Lipsticks b. Cold cream and vanishing cream c. Clear liquid shampoo d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

**Reference books (Theory)**

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman, Latest Edition
- b. Rowlings Text book of Pharmaceutics Latest Edition
- c. Tutorial Pharmacy – Cooper &Gun Latest Edition
- d. Remington's Pharmaceutical Sciences Latest Edition
- e. USP/BP/IP Latest Edition

**Scheme of Practical Examination :**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>