GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Bachelor of Pharmacy (B.Pharm)	Branch	-	Semester	VI	Version	3.0.0.0
Effective from	2020-2021	Effective for batches admitted onwards		2018-19			

S. N	Subject Code	Subject Name	Theory / Practical	Teaching Scheme								Examination Scheme						
				Credit				Hours Per Week				Theory Marks			Practical Marks			Total Marks
				Le	Tu	Pr	Total	Le	Tu	Pr	Total	CE	SE	ES	CE	SE	ES	
1	BPH601	Medicinal Chemistry III	Theory / Practical	3	1	2	6	3	1	4	8	10	15	75	10	15	75	200
2	BPH602	Pharmacology III	Theory / Practical	3	1	2	6	3	1	4	8	10	15	75	10	15	75	200
3	BPH603	Herbal Drug Technology	Theory / Practical	3	1	2	6	3	1	4	8	10	15	75	10	15	75	200
4	BPH604	Biopharmaceutics and Pharmacokintetics	Theory	3	1	0	4	3	1	0	4	10	15	75	0	0	0	100
5	BPH605	Industrial Pharmacy I	Theory / Practical	3	1	2	6	3	1	4	8	10	15	75	10	15	75	200
			Total	15	5	8	28	15	5	16	36	50	75	375	40	60	300	900

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Bachelor of Pharmacy	Branch/Spec.	B.Pharm.
Semester	VI	Version	3.0.0.0
Effective from Academic Year	2020-21	Effective for the batches admitted onwards	2018-19
Subject code	BP601TP	Subject Name	**Medicinal Chemistry III**

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	3	1	4	8	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	3	1	2	6	Practical	10	15	75	100	Practical	4 hr.	4 hr.

Pre-requisites

Nil

Scope and Objectives:

- This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs.
- The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD).
- The subject also emphasizes on the mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR) and synthesis of important drugs.

Learning Outcome:

Upon completion of the course student shall be able to

- Know the chemistry of drugs with respect to their biological activity.
- Understand the importance and different techniques of drug design and synthesis.
- Application of various methods in the synthesis of given medicinal compounds.
- Analysis of synthesized compounds for their better purification.
- Evaluate the physical parameters of synthesized compounds.
- Create skills in drawing structure and reactions using Chemdraw software.

Syllabus- Theory

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

Unit	Content	Hrs
1	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation, classification and important products of the following classes **β-Lactam antibiotics**: Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides**: Streptomycin, Neomycin, Kanamycin **Tetracyclines**: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	10
2	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes **Macrolide**: Erythromycin Clarithromycin, Azithromycin **Miscellaneous**: Chloramphenicol*, Clindamycin **Prodrugs**: Basic concepts and application of prodrugs design. **Antimalarials**: Etiology of malaria **Quinolines**: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil. **Miscellaneous**: Pyrimethamine, Artesunate, Artemether, Atovaquone.	10
3	**Anti-tubercular Agents** **Synthetic anti tubercular agents**: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Paraamino salicylic acid.* **Anti tubercular antibiotics**: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate **Urinary tract anti-infective agents** **Quinolones**: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin **Miscellaneous**: Furazolidone, Nitrofurantoin*, Methenamine **Antiviral agents**: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.	10

4	**Antifungal agents:** **Antifungal antibiotics**: Amphotericin-B, Nystatin, Natamycin, Griseofulvin Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoal Agents**: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintics**: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin. **Sulphonamides and Sulfones** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethazine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mafenide acetate, Sulfasalazine. **Folate reductase inhibitors**: Trimethoprim*, Cotrimoxazole. **Sulfones**: Dapsone*.	8
5	**Introduction to Drug Design** Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis Pharmacophore modeling and docking techniques. **Combinatorial Chemistry**: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.	7

Syllabus-Practical	
I	**Preparation of drugs and intermediates** 1. Sulphanilamide 2. 7-Hydroxy, 4-methyl coumarin 3. Chlorobutanol 4. Triphenyl imidazole 5. Tolbutamide 6. Hexamine
II	**Assay of drugs** 1. Isonicotinic acid hydrazide 2. Chloroquine 3. Metronidazole 4. Dapsone 5. Chlorpheniramine maleate 6. Benzyl penicillin
III	Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
IV	Drawing structures and reactions using chem draw®
V	Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeness screening (Lipinskies RO5)

Recommended books (Latest editions)	
1	Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry, 11th edition.
2	Foye's Principles of Medicinal Chemistry, 5th edition.
3	Burger's Medicinal Chemistry, Vol I to IV, 6th edition.
4	Introduction to principles of drug design- Smith and Williams.
5	Remington's Pharmaceutical Sciences, 21st edition.
6	Organic Chemistry by I.L. Finar, Vol. II
7	The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
8	Text book of practical organic chemistry- A.I.Vogel.
9	Martindale's extra pharmacopoeia, 35th edition.
10	Indian Pharmacopoeia.
11	Text book of Medicinal Chemistry by V. Alagarsamy, Vol 2.
12	Principles of Medicinal Chemistry by S. S. Kadam, K. R. Mahadik, K. K. Bothara, Vol I.

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Bachelor of Pharmacy	Branch/Spec.	B.Pharm.
Semester	VI	Version	3.0.0.0
Effective from Academic Year	2020-21	Effective for the batches admitted onwards	2018-19
Subject code	BPH602	Subject Name	**Pharmacology-III**

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	3	1	4	8	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	3	1	2	6	Practical	10	15	75	100	Practical	4 hr.	4 hr.

Pre-requisites

Nil

Scope and Objectives:

- This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,
- To emphasis on the principles of toxicology and chronopharmacology.

Learning Outcome:

Upon completion of the course student shall be able to

1. Know the pharmacological actions of different categories of drugs.
2. Understand the mechanism of drug action and its relevance in the treatment of different diseases.
3. Comprehend the principles of toxicology and treatment of various poisonings
4. Investigate the effect of drugs on animals using simulation software.
5. Demonstrate the various screening models and determination of toxicity using simulation software.
6. Appreciate correlation of pharmacology with related medical sciences.

Syllabus- Theory

Unit	Content	Hrs
1	**1. Pharmacology of drugs acting on Respiratory system** **a.** Anti -asthmatic drugs **b.** Drugs used in the management of COPD **c.** Expectorants and antitussives **d.** Nasal decongestants **e.** Respiratory stimulants **2. Pharmacology of drugs acting on the Gastrointestinal Tract** **a.** Antiulcer agents. **b.** Drugs for constipation and diarrhoea. **c.** Appetite stimulants and suppressants. **d.** Digestants and carminatives. **e.** Emetics and anti-emetics.	10
2	**Chemotherapy** **a.** General principles of chemotherapy. **b.** Sulfonamides and cotrimoxazole. **c.** Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	10
3	**Chemotherapy** **d.** Antitubercular agents **e.** Antileprotic agents **f.** Antifungal agents **g.** Antiviral drugs **h.** Anthelmintics **i.** Antimalarial drugs **j.** Antiamoebic agents	10
4	**1. Chemotherapy** **a.** Urinary tract infections and sexually transmitted diseases. **b.** Chemotherapy of malignancy. **2. Immunopharmacology** **a.** Immunostimulants **b.** Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	8
5	**1. Principles of toxicology** **a.** Definition and basic knowledge of acute, subacute and chronic toxicity. **b.** Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity **c.** General principles of treatment of poisoning **d.** Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning. **2. Chronopharmacology** **a.** Definition of rhythm and cycles. **b.** Biological clock and their significance leading to chronotherapy.	7

Syllabus - Practical

1.	Dose calculation in pharmacological experiments
2.	Antiallergic activity by mast cell stabilization assay
3.	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.

4.	Study of effect of drugs on gastrointestinal motility
5.	Effect of agonist and antagonists on guinea pig ileum
6.	Estimation of serum biochemical parameters by using semi- autoanalyser
7.	Effect of saline purgative on frog intestine
8.	Insulin hypoglycemic effect in rabbit
9.	Test for pyrogens (rabbit method)
10.	Determination of acute oral toxicity (LD50) of a drug from a given data
11.	Determination of acute skin irritation / corrosion of a test substance
12.	Determination of acute eye irritation / corrosion of a test substance
13.	Calculation of pharmacokinetic parameters from a given data
14.	Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15.	Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)
Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos	
Text books	
1	Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
2	Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
3	K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
4	Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
5	Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
6	Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
7	Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
8	N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.
Reference books	
1	Goodman and Gilman's, The Pharmacological Basis of Therapeutics
2	Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
3	Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Bachelor of Pharmacy	Branch/Spec.	B.Pharm.
Semester	VI	Version	3.0.0.0
Effective from Academic Year	2020-21	Effective for the batches admitted onwards	2018-19
Subject code	BPH603	Subject Name	**Herbal Drug Technology**

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	3	1	4	8	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	3	1	2	6	Practical	10	15	75	100	Practical	4 hr.	4 hr.

Pre-requisites

Nil

Scope and Objectives:

- This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc.
- The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Learning Outcome: Upon completion of the course student shall be able to

- Know various herbal raw material used in nutraceuticals, cosmetics, traditional medicines and other commercial purposes.
- Understand the formulation aspects and significance of various herbals.
- Application of various herbs in the formulations of nutraceuticals, cosmetics, traditional medicines.
- Analyse various nutraceuticals, cosmetics, traditional medicines.
- Evaluation of various herbal drugs as per WHO and ICH guidelines.
- Create the protocols for the standardisation and quality control of herbal drugs.

Syllabus- Theory

Unit	Content	Hrs
1	**Biodynamic Agriculture** Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.	3
2	**Indian Systems of Medicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asavas, Ghutika, Churna, Lehya and Bhasma.	7
3	**Nutraceuticals** General aspects, market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. **Study of following herbs as health food:** Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina	5
4	**Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. **Study of following drugs and their possible side effects and interactions:** Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.	3
5	**Herbal Cosmetics** Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.	4
6	**Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes. **Herbal formulations:** Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes	6
7	**Evaluation of Drugs:** WHO & ICH guidelines for the assessment of herbal drugs **Stability testing of herbal drugs.**	4
8	**Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.	6

	Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs	
9	**General Introduction to Herbal Industry** **Herbal drugs industry**: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. **Schedule T – Good Manufacturing Practice of Indian systems of medicine** Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.	7
Syllabus-Practical		
1	To perform preliminary phytochemical screening of crude drugs.	
2	Determination of the alcohol content of Asava and Arista	
3	Evaluation of excipients of natural origin	
4	Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.	
5	Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.	
6	Monograph analysis of herbal drugs from recent Pharmacopoeias	
7	Determination of Aldehyde content	
8	Determination of Phenol/Tannins content	
9	Determination of total alkaloids y various methods	
10	Determination of Bitter value	
11	Determination of foaming index & Swelling index	
Text books		
1	W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.	
2	Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.	
3	C.K. Kokate, Purohit, Gokhlae. Text book of Pharmacognosy, Gokhlae (2007), 37th Edition, Nirali Prakashan, Pune, 2007	
4	S. H. Ansari, Essentials of Pharmacognosy, IInd edition, Birla publications, New Delhi, 2007	
5	V.D.Rangari Pharmacognosy & Phytochemistry, Part I & II,1st Edition, 2009	
6	Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)	
7	Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.	

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Bachelor of Pharmacy	Branch/Spec.	B.Pharm.
Semester	VI	Version	3.0.0.0
Effective from Academic Year	2020-21	Effective for the batches admitted onwards	2018-19
Subject code	BPH604	Subject Name	**Biopharmaceutics and Pharmacokinetics**

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	3	1	0	4	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	3	1	0	4								

Pre-requisites

Nil

Scope and Objectives:

This subject is intended to impart the fundamental knowledge on various aspects related to biopharmaceutics of drugs including ADME process, pharmacokinetic parameters and models to study pharmacokinetics, bioavailability and bioequivalence.

Learning Outcome:

After successful completion of this subject, student get

- Know of basic concepts in Biopharmaceutics and pharmacokinetics and their significance.
- Understand the use of Biopharmaceutics and pharmacokinetics in development of optimum dosage regimen.
- Apply plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion and elimination.
- Analyze various pharmacokinetic model and data in the development of pharamceutical drug product.
- Compare various formulations by means of in vivo techniques like bioavailability and bioequivalence
- Create skill of using various pharmacokinetic parameters in solving pharmacokinetic problems.

Syllabus- Theory

Unit	Content	Hrs
1	**Introduction** **Biopharmaceutics to Absorption:** Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution**: Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs	10
2	**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs	10
3	**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a) Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extra vascular administrations. **Pharmacokinetics parameters** - K_E ,$t_{1/2}$,Vd, AUC, Ka, Cl_T and CL_R – Definitions, methods of eliminations, understanding of their significance and Applications	10
4	**Multicompartment models:** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings	08
5	**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Nonlinearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.	07

Text books

1. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi

Reference books

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi, Lea & Febiger publisher, 1977.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari. Mercel Dekker Inc., 2nd Edition, 1975.
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition. USA.

4	Pharmacokinetics: ByMilo Glbaldi Donald, R. Mercel Dekker Inc., 1982
5	Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press, 1983.
6	Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics by James Swarbrick, Lea & Febiger publisher, 1970.
7	Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995
8	Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9	Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
10	Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia, 1975

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Bachelor of Pharmacy	Branch/Spec.	B.Pharm.
Semester	VI	Version	3.0.0.0
Effective from Academic Year	2020-21	Effective for the batches admitted onwards	2018-19
Subject code	BPH605	Subject Name	**Industrial Pharmacy I**

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	3	1	4	8	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	3	1	2	6	Practical	10	15	75	100	Practical	4 hr.	4 hr.

Pre-requisites

Nil

Scope and Objectives:

This subject is intended to give the knowledge on various aspects related to design, development, evaluation and applications of different types of dosage forms.

Learning Outcome:

- Know various pharmaceutical formulations and their manufacturing techniques.
- Understand considerations in preformulation and formulation development with respect to the pharmaceutical industry.
- Apply theoretical concepts in order to develop lucid ideas about the use of various equipment in laboratory relevant to pharmaceutical products.
- Compare different dosage forms on the basis of their merits and demerits for their selection according to drug.
- Perform preformulation evaluation as well as evaluation of formulations, such as tablets, capsules, parenteral products and cosmetics.
- Formulate dosage forms, such as tablets, capsules, injections, ophthalmic products, creams, etc.

Syllabus- Theory

Unit	Contents	Hrs
1.	**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	06
2.	**Tablets:** a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. Quality control tests: In process and finished product tests **Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia.	12
3.	**Capsules:** a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules. b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. c. Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets.	07
4.	**Parenteral Products:** a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity. b. Production procedure, production facilities and controls, aseptic processing. c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality	10

	control tests of parenteral products. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations.	
5.	**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. **Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. **Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests**.**	10
Syllabus-Practical		
1.	Preformulation studies on paracetamol/asparin/or any other drug.	
2.	Preparation and evaluation of Paracetamol tablets.	
3.	Preparation and evaluation of Aspirin tablets.	
4.	Coating of tablets- film coating of tables/granules.	
5.	Preparation and evaluation of Tetracycline capsules.	
6.	Preparation of Calcium Gluconate injection.	
7.	Preparation of Ascorbic Acid injection	
8.	Qulaity control test of (as per IP) marketed tablets and capsules.	
9.	Preparation of Eye drops/ and Eye ointments.	
10.	Preparation of Creams (cold / vanishing cream).	
11.	Evaluation of Glass containers (as per IP)	
Text books		
1.	Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz.	
2.	Theory and Practice of Industrial Pharmacy by Liberman & Lachman.	
3.	Cosmetic Science & Technology Volume 1-3 by M.S. Balsam.	
4.	Cosmetics Formulation Manufactoring & Quiality Control by P.P. Sharma.	
5.	Handbook of Pharmaceutical Technology by L. K. Ghosh.	
6.	Handbook of Cosmetics by B.M. Mithal.	
7.	Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005.	
Reference books		
1.	Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.	
2.	Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman.	
3.	Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition.	
4.	Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS).	
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