Shri Rawatpura Sarkar University, Raipur

Examination Scheme & Syllabus

for

BACHELOR IN PHARMACY

SEMESTER -VI

(Effective from the session: 2019-20)

Faculty of Pharmacy
Shri Rawatpura Sarkar University, Raipur
BACHELOR OF PHARMACY
SEMESTER -VI
Examination Scheme
(Effective from the session: 2019-20)

Sr. No.	Subject Code	Name of the Course with PCI code	Internal assessment				Teaching hours per week			Credit	End semester exams			Total Marks
			TA	Sessional exams										
				CT	Duration	Total	L	T	P		Marks		Duration	
1	BPH601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
2	BPH602T	Pharmacology III – Theory BP602T	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
3	BPH603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
4	BPH604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
5	BPH605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
6	BPH606T	Quality Assurance– Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
7	BPH607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15			4	2	35	15	4 Hrs	50

8	BPH608P	Pharmacology III – Practical	5	10	4 Hrs	15			4	2	35	15	4 Hrs	50
9	BPH609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15			4	2	35	15	4 Hrs	50
			75	120	18 Hrs	195	Total 30				555	195	30 Hrs	750

*The subject experts at college level shall conductexaminatio

<table>
<tr><td>Course Title</td><td colspan="5">Medicinal Chemistry III – Theory</td></tr>
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<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the course student shall be able to

1.Understand the importance of drug design and different techniques of drug design.

2.Understand the chemistry of drugs with respect to their biological activity.

3.Know the metabolism, adverse effects and therapeutic value of drugs.

4.Know the importance of SAR of drugs.</td></tr>
<tr><td>Course Contents</td><td colspan="6">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 by (*)

UNIT – I 10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the followingclasses.

▪ β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams
▪ Aminoglycosides: Streptomycin, Neomycin, Kanamycin
▪ Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline,Doxycycline

UNIT – II 10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the followingclasses.

▪ Macrolide: Erythromycin Clarithromycin, Azithromycin.
▪ Miscellaneous: Chloramphenicol*, Clindamycin.
▪ Prodrugs: Basic concepts and application of prodrugs design.</td></tr>
</table>

- **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, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

- **Synthetic anti tubercular agents:** Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid. *
- **Anti-tubercular antibiotics:** Rifampicin, Rifabutin, CycloserineStreptomycine, Capreomycinsulphate.
- **Urinary tract anti-infective agents**
- **Quinolones:** SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin
- **Miscellaneous:** Furazolidine, Nitrofurantoin*, Methanamine.
- **Antiviral agents:**
- Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT– IV **08 Hours**

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, Praziquantal, Ivermectin.
- **Sulphonamides and Sulfones**
- Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine,

	Mefenide acetate, Sulfasalazine. ▪ **Folate reductase inhibitors:** Trimethoprim*, Cotrimoxazole. ▪ **Sulfones:** Dapsone*. **UNIT – V** **07 Hours** **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 Hanschanalysis. Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.
Course Outcomes	1. To develop an understanding of the physico-chemical properties of drugs. 2. To understand how current drugs were developed by using pharmacophore modeling and docking technique. 3. To acquire knowledge in the chemotherapy for cancer and microbial diseases and different anti-viral agents. 4. To acquire knowledge about the mechanism pathways of different class of medicinal compounds. 5. To have been introduced to a variety of drug classes and some pharmacological properties. 6. To acquire knowledge on thrust areas fir further research.
Text Books	1.Wilson and Griswold's Organic medicinal and Pharmaceutical Chemistry. 2.Foye's Principles of Medicinal Chemistry. 3.Burger's Medicinal Chemistry, Vol I to IV.
Reference Books	1.Introduction to principles of drug design- Smith and Williams. 2.Remington's Pharmaceutical Sciences. 3.Martindale's extra pharmacopoeia.

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<table>
<tr><td>Course Title</td><td colspan="5">Pharmacology III – Theory</td></tr>
<tr><td>Course Code</td><td colspan="3">BPH602T</td><td colspan="2">Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of this course the student should be able to:
1.Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2.Comprehend the principles of toxicology and treatment of various poisoningsand
3.Appreciate correlation of pharmacology with related medical sciences.</td></tr>
<tr><td>Course Contents</td><td colspan="6">UNIT-I 10hours
1. Pharmacology of drugs acting on Respiratory system
a. Anti -asthmaticdrugs
b. Drugs used in the management ofCOPD
c. Expectorants andantitussives
d. Nasaldecongestants
e. Respiratorystimulants
2. Pharmacology of drugs acting on the GastrointestinalTract
a. Antiulceragents.
b. Drugs for constipation anddiarrhoea.
c. Appetite stimulants andsuppressants.
d. Digestants andcarminatives.
e. Emetics andanti-emetics.</td></tr>
</table>

UNIT-II **10hours**

3. Chemotherapy

a. General principles ofchemotherapy.

b. Sulfonamides andcotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol,macrolides, quinolones and fluoroquinolins, tetracycline andaminoglycosides

UNIT-III10hours

3. Chemotherapy

a. Antitubercularagents

b. Antileproticagents

c. Antifungalagents

d. Antiviral drugs

e. Anthelmintics

f. Antimalarialdrugs

g. Antiamoebicagents

UNIT-IV **08hours**

3. Chemotherapy

1. Urinary tract infections and sexually transmitteddiseases.
2. Chemotherapy ofmalignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V **07hours**

5. Principles of toxicology

	a. Definition and basic knowledge of acute, subacute and chronictoxicity. b. Definition and basic knowledge of genotoxicity, carcinogenicity,teratogenicity and mutagenicity c. General principles of treatment ofpoisoning d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenicpoisoning. **6. Chronopharmacology** a. Definition of rhythm andcycles. b. Biological clock and their significance leading tochronotherapy.
Course Outcomes	1. Students would have studied elaborately on mechanism of drug action and its relevance in the treatment of different infectious diseases 2. They comprehended the principles of toxicology and treatment of various poisonings and 3. They came across the methods of toxicity studies 4. They studied about symptoms of several poisonings 5. They studied about treatment of several poisonings 6. Students understood the toxicity profile of each drugs
Text Books	1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale'sPharmacology, Churchil LivingstoneElsevier 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, TataMc Graw-Hill 3. Goodman and Gilman's, The Pharmacological Basis ofTherapeutics 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams &Wilkins 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

Reference Books	1. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE BrothersMedical Publishers (P) Ltd, NewDelhi. 2. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig&Robert, 3. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata, 4. Kulkarni SK. Handbook of experimental pharmacology.VallabhPrakashan, 5. N.Udupa and P.D. Gupta, Concepts inChronopharmacology.

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<tr><td>Course Title</td><td colspan="5">Herbal Drug Technology –Theory</td></tr>
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<tr><td>Prerequisites</td><td colspan="6">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of this course the student should be able to:
1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. Appreciate patenting of herbal drugs, GMP.</td></tr>
<tr><td>Course Contents</td><td colspan="6">UNIT-I 6 Hours
Herbs as raw materials
Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs
Selection, identification and authentication of herbal materials Processing of herbal raw material
Biodynamic Agriculture
Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.
UNIT-II 5 Hours
a) Basic principles involved in Ayurveda, Siddha, Unani andHomeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas andAsawas, Ghutika,Churna, Lehya andBhasma.
UNIT-III 7 Hours
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</td></tr>
</table>

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

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.

UNIT-IV **10 Hours**

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.

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

UNIT-V **10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

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.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

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	UNIT-VI **07 Hours** **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 equipments, standard operating procedures, health and hygiene, documentation and records.
Course Outcomes	1. The aim of the degree course is to provide graduates with a good knowledge of the basic and applied know-how and professional skills in Herbal drug Science and Technology and the necessary training for admission to the postgraduate courses in this field. 2. They will acquire operative know-how and be able to carry out technical and 3. management tasks and professional activities in the areas of transformation of 4. medicinal herbs, management of the quality of the processes, marketing of 5. medicinal plants and derivatives for use in herbal, food and cosmetic products, 6. Guaranteeing conformity with the national and EU laws in force. 7. At the end of the course, the graduate will have acquired the following know-how and skills: The recognition, collection and preservation of medicinal plants. ▪ Analyses and dosage of active ingredients. ▪ The biological effects of medicinal plants. ▪ The toxicological aspects of active ingredients and finished products. ▪ The study, design, management, control and conduction of the processing.

Text Books	1. Textbook of Pharmacognosy by Trease &Evans. 2. Textbook of Pharmacognosy by Tyler, Brady &Robber. 3. Pharmacognosy by Kokate, Purohit andGokhale 4. Essential of Pharmacognosy byDr.S.H.Ansari
Reference Books	1. Pharmacognosy & Phytochemistry byV.D. Rangari 2. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine &Homeopathy) 3. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

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<table>
<tr><td>Course Title</td><td colspan="5">Biopharmaceutics and Pharmacokinetics – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH604T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2" rowspan="2">Total marks in the end semester: 75
Minimum of class tests to be conducted: 02</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.

2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.

3. Critically evaluate biopharmaceutic studies involving drug product equivalency

4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

5. Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them</td></tr>
<tr><td>Course Contents</td><td colspan="6">UNIT-I 10Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding.

Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT-II 10 Hours

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the

bioavailability.

UNIT-III 10 Hours</td></tr>
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	Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascularadministrations, calculations of Ka, K_E. From plasma and urinary excretion data **UNIT-IV** **08 Hours** **Multicompartment models:** Two compartment open model. IV bolus **Multiple – Dosage Regimens**: a). Repititive Intravenous injections – One Compartment Open Model b). Repititive Extravascular dosing – One Compartment Open model **UNIT-V** **07 Hours** **Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Biotransformation of drugs.
Course Outcomes	After successful completion of the course student will be able to: 1. Understand the concept of ADME of drug in human body. 2. Determine the various pharmacokinetic parameters from either plasma concentration or urinary excretion data for drug 3. Apply the various regulations related to developing BA-BE study protocol for the new drug molecule.
Text Books	1. Biopharmaceutics and Clinical Pharmacokinetics by, MiloGibaldi. 2. Biopharmaceutics and Pharmacokinetics; By Robert FNotari 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernationaledition.USA 4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,VallabhPrakashan Pitampura,Delhi 5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel DekkerInc. 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott

	by ADIS Health Science Press.
Reference Books	1. Biopharmaceutics; BySwarbrick 2. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowlandand 3. Thomas, N. Tozen, Lea and Febrger, Philadelphia,1995. 4. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M,Mack, Publishing Company,Pennsylvania1989. 5. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel,1987. 6. Remington's Pharmaceutical Sciences, By Mack PublishingCompany, Pennsylvnia

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<tr><td>Course Title</td><td colspan="5">Pharmaceutical Biotechnology– Theory</td></tr>
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<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
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<tr><td>Prerequisites</td><td colspan="6">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the subject student shall be able to;
1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology</td></tr>
<tr><td>Course Contents</td><td colspan="6">Unit I10 Hours
a) Brief introduction to Biotechnology with reference to PharmaceuticalSciences.
b) Enzyme Biotechnology- Methods of enzyme immobilization andapplications.
c) Biosensors- Working and applications of biosensors in PharmaceuticalIndustries.
d) Brief introduction to ProteinEngineering.
e) Use of microbesin industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease,Penicillinase.
f) Basic principles of geneticengineering.
Unit II10 Hours
a) Study of cloning vectors, restriction endonucleases and DNAligase.
b) Recombinant DNA technology. Application of genetic engineering inmedicine.
c) Application of r DNA technology and genetic engineering in theproducts:
d) Interferon b) Vaccines- hepatitis- B c) Hormones-Insulin.
e) Brief introduction toPCR
Types of immunity- humoral immunity, cellular immunity
Unit III10 Hours
a) Structure ofImmunoglobulins
b) Structure and Function ofMHC
c) Hypersensitivity reactions, Immune stimulation and Immunesuppressions.
d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine,</td></tr>
</table>

	antitoxins, serum-immune blood derivatives and other products relative toimmunity. e) Storage conditions and stability of officialvaccines f) Hybridoma technology- Production, Purification andApplications **Unit IV08Hours** a) Immuno blotting techniques- ELISA, Western blotting, Southernblotting. b) Genetic organization of Eukaryotes andProkaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation. **Unit V 07 Hours** a. Types ofmutation/mutants b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process,stirring. c) Large scale production fermenter design and its variouscontrols. Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
Course Outcomes	1. Pharmaceutical biotechnology introduces the concepts like DNA, rDNA technology, site directed mutagenesis to the students and thereby also helps in their further learning and project planning. 2. The use of different protein purification techniques and their use in pharmaceutical and biotechnological fields are given on a practical and theoretical basis. This helps them in project planning as well as in further studies.
Text Books	1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press WashingtonD.C. 2. RA Goldshy et. al.,KubyImmunology. 3. J.W. Goding: MonoclonalAntibodies. 4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society ofChemistry.
Reference Books	1. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio. 2. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication. 3. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

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<tr><td>Course Title</td><td colspan="5">Quality Assurance– Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH606T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
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<tr><td>Prerequisites</td><td colspan="6">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the course student shall be able to:
1. understand the cGMP aspects in a pharmaceutical industry
2. appreciate the importance of documentation
3. understand the scope of quality certifications applicable to pharmaceutical industries
4. understand the responsibilities of QA & QC departments</td></tr>
<tr><td>Course Contents</td><td colspan="6">UNIT – I10 Hours
Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP
Total Quality Management (TQM): Definition, elements, philosophies
ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testingguidelines
Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedure

UNIT – II10 Hours
Organization and personnel: Personnel responsibilities, training, hygiene and personal records.
Premises: Design, construction and plant layout, maintenance, sanitation, environmental
control, utilities and maintenance of sterile areas, control of contamination.
Equipments and raw materials: Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT– III 10 Hours
Quality Control: Quality control test for containers, rubber closures and secondary packing materials.
Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports,</td></tr>
</table>

	Disqualification of Testing Facilities **UNIT– IV** **08 Hours** **Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records. **UNIT– V** **07 Hours** **Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management
Course Outcomes	1. The students understand the importance of quality in pharmaceutical products. 2. The students is explored into importance of Good practices such as GMP,GLP etc. 3. The factors affecting the quality of pharmaceutical is explored. 4. He understands the regulatory aspects of pharmaceutical taught to the student. 5. The process involved in manufacturing of pharmaceuticals different section/department and activity is learnt. 6. The various documentation process is highlighted to the student.
Text Books	1. Quality Assurance Guide by organization of Pharmaceutical Products ofIndia. 2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69. 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHOPublications. 4. A guide to Total Quality Management- Kushik Maitra and Sedhan KGhosh 5. How to Practice GMP's – P P Sharma.
Reference Books	1. ISO 9000 and Total Quality Management – Sadhank GGhosh 2. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms 3. Good laboratory Practices – Marcel DeckkerSeries 4. ICH guidelines, ISO 9000 and 14000guidelines

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<table>
<tr><td>Course Title</td><td colspan="5">Medicinal chemistry III – Practical</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH607P</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td>Total marks in the end semester: 35</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td><td></td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the course student shall be able to
1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.</td></tr>
<tr><td>Course Contents</td><td colspan="5">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</td></tr>
</table>

	IIIPreparation 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 likeliness screening (Lipinskies RO5)
Course Outcomes	1. Understand how to make correct use of various equipments& take safety measures while working in medicinal chemistry laboratory. 2. Develop skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography. 3. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds. 4. To interpret the spectral characterizations made by IR and 1H-NMRs of synthesized compounds.
Text Books	1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry. 2. Foye's Principles of Medicinal Chemistry. 3. Burger's Medicinal Chemistry, Vol I to IV.
Reference Books	1. Introduction to principles of drug design- Smith and Williams. 2. Remington's Pharmaceutical Sciences. 3. Martindale's extra pharmacopoeia.

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<table>
<tr><td>Course Title</td><td colspan="5">Pharmacology III – Practical</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH608P</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td>Total marks in the end semester: 35</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td><td></td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of this course the student should be able to:
1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoning sand
3. Appreciate correlation of pharmacology with related medical sciences.</td></tr>
<tr><td>Course Contents</td><td colspan="5">1. Dose calculation in pharmacologicalexperiments
2. Antiallergic activity by mast cell stabilizationassay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat modeland NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinalmotility
5. Effect of agonist and antagonists on guinea pigileum
6. Estimation of serum biochemical parameters by using semi-autoanalyser
7. Effect of saline purgative on frogintestine
8. Insulin hypoglycemic effect inrabbit
9. Test for pyrogens (rabbitmethod)
10. Determination of acute oral toxicity (LD50) of a drug from a givendata
11. Determination of acute skin irritation / corrosion of a testsubstance
12. Determination of acute eye irritation / corrosion of a testsubstance
13. Calculation of pharmacokinetic parameters from a givendata
14. Biostatistics methods in experimental pharmacology(student’s t test,ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test,</td></tr>
</table>

	Wilcoxon Signed Ranktest) *Experiments are demonstrated by simulated experiments/videos
Course Outcomes	1. Understand the OECD guidelines (425) for acute oral toxicity. 2. Introduction to principles of bioassay, its types including advantages and disadvantages. 3. Determination of unknown concentration of Acetylcholine and Histamine using suitable isolated tissue preparations (Matching bioassay method). 4. Determination of unknown concentration of Acetylcholine and Histamine using suitable isolated tissue preparations (Bracketing bioassay method). 5. Determination of unknown concentration of Acetylcholine and Histamine using suitable isolated tissue preparations (Interpolation bioassay method). 6. Study the analgesic activity by using Eddy's hot plate Analgesiometer in mice.
Text Books	1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale'sPharmacology, Churchil LivingstoneElsevier 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, TataMc Graw-Hill 3. Goodman and Gilman's, The Pharmacological Basis ofTherapeutics 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams &Wilkins 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
Reference Books	1. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE BrothersMedical Publishers (P) Ltd, NewDelhi. 2. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig&Robert, 3. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata, 4. Kulkarni SK. Handbook of experimental pharmacology.VallabhPrakashan, 5. N.Udupa and P.D. Gupta, Concepts inChronopharmacology.

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<table>
<tr><td>Course Title</td><td colspan="5">Herbal Drug Technology – Practical</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH609P</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 35</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamental studied in previous class in B.Pharm.</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of this course the student should be able to:
1.understand raw material as source of herbal drugs from cultivation to herbal drug product
2.know the WHO and ICH guidelines for evaluation of herbal drugs
3.know the herbal cosmetics, natural sweeteners, nutraceuticals
4.Appreciate patenting of herbal drugs, GMP.</td></tr>
<tr><td>Course Contents</td><td colspan="5">1. To perform preliminary phytochemical screening of crudedrugs.
2. Determination of Ashvalue
3. Determination of moisture content of crudedrugs
4. Determination of Extractive values of crudedrugs
5. Determination of the alcohol content of Asava andArista
6. Preparation of herbal cosmetics
7. Preparation and standardization of herbalformulation
8. Determination of swelling index and foamingindex
9. Monograph analysis of herbal drugs from recentPharmacopoeias
10. Analysis of fixed oils</td></tr>
<tr><td>Course Outcomes</td><td colspan="5">1. Prepare, label & evaluate herbal/TSM formulations.
2. Evaluate marketed cosmetic & nutraceutical formulations.
3. Conduct pre-formulation parameters & understand underlying rationale.
4. Conduct in vitro assays for correlation with biological efficacy.</td></tr>
</table>

Text Books	1. Textbook of Pharmacognosy by Trease &Evans. 2. Textbook of Pharmacognosy by Tyler, Brady &Robber. 3. Pharmacognosy by Kokate, Purohit andGokhale 4. Essential of Pharmacognosy byDr.S.H.Ansari
Reference Books	1. Pharmacognosy & Phytochemistry byV.D.Rangari 2. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine &Homeopathy) 3. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.