GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

SCHEME OF TEACHING

Course Code	Name of the Course	No. of Hours	Tutorial	Credit Points
BP601T	Medicinal Chemistry-III (Theory)	3	1	4
BP602T	Pharmacology-III (Theory)	3	1	4
BP603T	Herbal Drug Technology (Theory)	3	1	4
BP604T	Industrial Pharmacy-II (Theory)	3	1	4
BP605T	Pharmaceutical Biotechnology (Theory)	3	1	4
BP601P	Medicinal Chemistry-III (Practical)	4	-	2
BP602P	Pharmacology-III (Practical)	4	-	2
BP603P	Herbal Drug Technology (Practical)	4	-	2
	Total	**27**	**5**	**26**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

SCHEME OF EVALUATION

Course Code	Name of the Course	Marks Distribution			
		University (End Semester Exam)	Institute		Total
			Sessional Exams	Continuous Mode	
BP601T	Medicinal Chemistry-III (Theory)	75	15	10	100
BP602T	Pharmacology-III (Theory)	75	15	10	100
BP603T	Herbal Drug Technology (Theory)	75	15	10	100
BP604T	Industrial Pharmacy-II (Theory)	75	15	10	100
BP605T	Pharmaceutical Biotechnology (Theory)	75	15	10	100
BP601P	Medicinal Chemistry-III (Practical)	35	10	5	50
BP602P	Pharmacology-III (Practical)	35	10	5	50
BP603P	Herbal Drug Technology (Practical)	35	10	5	50
Total		**480**	**105**	**65**	**650**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP601T	Subject Title: Medicinal Chemistry-III (Theory)
Pre-requisite: -	

Scope: 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 chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Course Objectives:

Upon completion of the course the 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

Teaching Scheme (Hours per week)			Evaluation Scheme (Marks)			
			Theory			Total
Lecture	Tutorial	Credit	University Assessment	Continuous Assessment	Internal Assessment	
3	1	4	75	10	15	100

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 (*)

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline.	**10 Hours**	**22.22%**
2.	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **Macrolide:** Erythromycin Clarithromycin, Azithromycin.	**10 Hours**	**22.22%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Sr. No.	UNIT	Hours	Weightage (%)
	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, Artesunete, Artemether, Atovoquone.		
3.	**Anti-tubercular Agents:** **Synthetic anti tubercular agents:** Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* **Antitubercular 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:** Furazolidine, Nitrofurantoin*, Methanamine. **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	**10 Hours**	**22.22%**
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, 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*.	**08 Hours**	**17.77%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Sr. No.	UNIT	Hours	Weightage (%)
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.	**07 Hours**	**15.55%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP601P	Subject Title: Medicinal Chemistry-III (Practical)
Pre-requisite: --	

Teaching Scheme (Hours per week)		Evaluation Scheme (Marks)			
		Theory			
Practical	Credit	University Assessment	Continuous Assessment	Internal Assessment	Total
4	2	35	5	10	50

List of Practical:

Sr. No.	Title of the Experiments
1	**Preparation of drugs and intermediates:** 1. Sulphanilamide 2. 7-Hydroxy, 4-methyl coumarin 3. Chlorobutanol 4. Triphenyl imidazole 5. Tolbutamide 6. Hexamine
2	**Assay of drugs** 1. Isonicotinic acid hydrazide 2. Chloroquine 3. Metronidazole 4. Dapsone 5. Chlorpheniramine maleate 6. Benzyl penicillin
3	Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
4	Drawing structures and reactions using chem draw®
5	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)

Recommended Books (Latest Editions)

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.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP602T	Subject Title: Pharmacology-III (Theory)
Pre-requisite: --	

Scope: 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, emphasis on the principles of toxicology and chrono pharmacology.

Course Objective: Upon completion of this course, the students would be able to

1. Understand the mechanism of drug action and its relevance in the treatment of
2. Different infectious diseases
3. Comprehend the principles of toxicology and treatment of various poisoning and appreciate correlation of pharmacology with related medical sciences.

Teaching Scheme (Hours per week)			Evaluation Scheme (Marks)			
			Theory			Total
Lecture	Tutorial	Credit	University Assessment	Continuous Assessment	Internal Assessment	
3	1	4	75	10	15	100

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
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 **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 Hours**	**22.22%**
2.	**Chemotherapy** a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	**10 Hours**	**22.22%**
3.	**Chemotherapy** a. Antitubercular agents	**10 Hours**	**22.22 %**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Sr. No.	UNIT	Hours	Weightage (%)
	b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e. Anthelmintics f. Antimalarial drugs g. Antiamoebic agents		
4.	**Chemotherapy** l. Urinary tract infections and sexually transmitted diseases. m. Chemotherapy of malignancy. **Immunopharmacology** a. Immunostimulants b. Immunosuppressant: Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	**8 Hours**	**17.77 %**
5.	**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. **Chrono pharmacology** a. Definition of rhythm and cycles. b. Biological clock and their significance leading to chronotherapy.	**07 Hours**	**15.55%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP602P	Subject Title: Pharmacology-III (Practical)
Pre-requisite: --	

Teaching Scheme (Hours per week)		Evaluation Scheme (Marks)			
		Theory			
Practical	Credit	University Assessment	Continuous Assessment	Internal Assessment	Total
4	2	35	5	10	50

List of Practical:

Sr. No.	Title of the Experiments
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- auto analyser
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)

***Experiments are demonstrated by simulated experiments/videos**

Recommended Books: (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
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

6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher, Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP603T	Subject Title: Herbal Drug Technology (Theory)
Pre-requisite: --	

Scope: 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.

Objectives: 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, and nutraceuticals.
4. Appreciate patenting of herbal drugs, GMP.

Teaching Scheme (Hours per week)			Evaluation Scheme (Marks)			
			Theory			
Lectures	Tutorial	Credit	University Assessment	Continuous Assessment	Internal Assessment	Total
3	1	4	75	10	15	100

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**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. **Indian Systems of Medicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.	**10 Hours**	**22.22%**
2.	**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.	**10 Hours**	**22.22%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Sr. No.	UNIT	Hours	Weightage (%)
	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.	**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	**10 Hours**	**22.22%**
4.	**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.	**10 Hours**	**22.22%**
5.	**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.	**7 Hours**	**15.55%**

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP603P	Subject Title: Herbal Drug Technology (Practical)
Pre-requisite: -	

Teaching Scheme (Hours per week)		Evaluation Scheme (Marks)			
		Theory			
Practical	Credit	University Assessment	Continuous Assessment	Internal Assessment	Total
4	2	35	5	10	50

List of Practical:

Sr. No.	Title of the Experiments
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 content
9.	Determination of Total Alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr. S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeial 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.

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP604T	Subject Title: Industrial Pharmacy-II (Theory)
Pre-requisite: --	

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:
1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Teaching Scheme (Hours per week)			Evaluation Scheme (Marks)			
			Theory			Total
Lecture	Tutorial	Credit	University Assessment	Continuous Assessment	Internal Assessment	
3	1	4	75	10	15	100

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Pilot plant scale up techniques:** General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	**10 Hours**	**22.22%**
2.	**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	**10 Hours**	**22.22%**
3.	**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and	**10 Hours**	**22.22%**

Sr. No.	UNIT	Hours	Weightage (%)
	Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.		
4.	**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.	**8 Hours**	**17.77%**
5.	**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	**7 Hours**	**15.55%**

Recommended Books (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.html.

GANDHINAGAR INSTITUTE OF PHARMACY
BACHELOR OF PHARMACY
B. PHARM SEMESTER VI (THIRD YEAR)

Subject Code: BP605T	Subject Title: Pharmaceutical Biotechnology (Theory)
Pre-requisite: -	

Scope: Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting. Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs. Biotechnology has already produced transgenic crops and animals and the future promises lot more. It is basically a research-based subject.

Objectives: 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

Teaching Scheme (Hours per week)			Evaluation Scheme (Marks)			
			Theory			Total
Lecture	Tutorial	Credit	University Assessment	Continuous Assessment	Internal Assessment	
3	1	3	75	10	15	100

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme Biotechnology- Methods of enzyme immobilization and applications. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries. d) Brief introduction to Protein Engineering. e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering.	10 Hours	22.22%
2.	Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii)	10 Hours	22.22%

	Hormones-Insulin.) Brief introduction to PCR		
3.	Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation, and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substitutes.	**10 Hours**	**22.22%**
4.	a) Immunoblotting techniques-ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation/mutants.	**8 Hours**	**17.77%**
5.	a.) Fermentation methods and general requirements, study of media, equipment, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillin, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.	**7 Hours**	**15.55%**

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi.