

**Proposed
New Scheme**

of

**M.PHARM.
2013-14**

Scheme & Syllabus of M.PHARM. 2013-14

**Scheme & Syllabus of
B. Pharm., M.PHARM & Ph.D.**

SESSION: 2013-14**M. Pharm. Course: FIRST SEMESTER**

S. No.	Name of School	Compulsory Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Course I	PHSC-1201 Methods in Pharmaceutical Research (MPR)		4	-	-	4
		Course II	PHSC-1202	Product Development	4	-	-	4
		Course III	PHSC-1203	Pharmaceutical Biotechnology	4	-	-	4
		Course IV	PHSC-1204	MPR Practicals	-	8	3	3
		Course V	PHSC-1205	Product Development Practicals	-	8	3	3
		Course VI	PHSC-1206	Pharmaceutical Biotechnology Practicals	-	8	3	3
				Total Credits	12	24	9	21

SESSION: 2013-14**M. Pharm. Course: SECOND SEMESTER: Specialization: Pharmaceutics**

S. No.	Name of School	Compulsory Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Course I	PHSC-2201	Advanced Pharmaceutics	4	-	-	4
		Course II	PHSC-2202	Biopharmaceutics and Pharmacokinetics	4	-	-	4
		Course III	PHSC-2203	Novel Drug Delivery System (NDDS)	4	-	-	4
		Course IV	PHSC-2204	Advanced Pharmaceutics Practicals	-	-	16	5
		Course V	PHSC-2205	DRA/IPR and QA	4			4
		Dissertation Project PHSC-2206		Dissertation Project				4
				Total Credits	16		16	25

SESSION: 2013-14**M. Pharm. Course: SECOND SEMESTER : Specialization: Pharmaceutical Chemistry**

S. No.	Name of School	Compulsory Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Course I	PHSC-2207	Drug Design and Discovery	4	-	-	4
		Course II	PHSC-2208	Advances in Medicinal Chemistry	4	-	-	4
		Course III	PHSC-2209	Advanced Organic Chemistry	4	-	-	4
		Course IV	PHSC-2210	Advanced Pharmaceutical Chemistry Practicals	-	-	16	5
		Course V	PHSC-2205	DRA/IPR and QA	4			4
		Dissertation Project PHSC - 2211		Dissertation Project				4
				Total Credits	16		16	25

SESSION: 2013-14**M. Pharm. Course: SECOND SEMESTER: Specialization: Pharmacognosy**

S. No.	Name of School	Compulsory Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Course I	PHSC-2212	Natural Products	4	-	-	4
		Course II	PHSC-2213	Advanced Pharmacognosy	4	-	-	4
		Course III	PHSC-2214	Plant Biotechnology	4	-	-	4
		Course IV	PHSC-2215	Advanced Pharmacognosy Practical	-	-	16	5
		Course V	PHSC-2205	DRA/IPR and QA	4			4
		Dissertation Project PHSC-2216		Dissertation Project				4
				Total Credits	16		16	25

SESSION: 2013-14**M. Pharm. Course: SECOND SEMESTER: Specialization: Pharmaceutical Biotechnology**

S. No.	Name of School	Compulsory Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Course I	PHSC-2217	Advanced Biotechnology	4	-	-	4
		Course II	PHSC-2218	Molecular Biology And Genetic Engineering	4	-	-	4
		Course III	PHSC-2219	Industrial Biotechnology	4	-	-	4
		Course IV	PHSC-2220	Pharmaceutical Biotechnology Practical	-	-	16	5
		Course V	PHSC-2205	DRA/IPR/QA	4			4
		Dissertation Project PHSC - 2221		Dissertation Project*				4
				Total Credits	16		16	25

- Syllabus to be prepared under the guidance of the Supervisor for the Project to be carried out during III and IV Semester.

M. Pharm. Course: THIRD SEMESTER: SESSION: 2013-14
Specialization: Pharmaceutics/ Pharmaceutical Chemistry/ Pharmacognosy/ Pharmaceutical Biotechnology

S. No.	Name of School	Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)	Elective I,II,III,IV	PHSE-3201,3202,3203,3204	Elective I *	3	-	-	3
		Project Major	PHSC - 3205	Project Major	-	-	12	12
		Project Minor	PHSC - 3206	Project Minor	-	-	-	05
				Total Credits	3		12	20

*** Elective Papers & Course Code:**

1. Cosmeticology : PHSE-3201
2. Immunology and Immunoassays : PHSE-3202
3. Phytopharmaceuticals and Nutraceuticals : PHSE-3203
4. Advanced Pharm. Chemistry : PHSE-3204

- Minor & Major Project Valuation by Internal Examiner

M. Pharm. Course: FOURTH SEMESTER: SESSION: 2013-14
Specialization: Pharmaceutics/ Pharmaceutical Chemistry/ Pharmacognosy/ Pharmaceutical Biotechnology

S. No.	Name of School	Course	Course Code	Name of Course	Per Week Load			
					L	T	P	C
1	School of Engineering and Technology (EAT)		PHSC-4201	Project Major	-	-	-	20
				Total Credits	-		-	20

- * Major Project Valuation by Internal Examiner

**Proposed New
SYLLABUS
OF
M.PHARM.
2013-14**

M.PHARM.-I SEMESTER: COMPULSORY (2013-14)
COURSE –I : METHODS IN PHARMACEUTICAL RESEARCH (THEORY)

Course Code : PHSC-1201

04hrs/week

Unit-I (12 Hrs.):

Basic theoretical background of NMR spectroscopy, interpretation of PMR spectra of common organic compound, Basics of ¹³C-NMR and 2 D NMR with applications.

Unit-II (12 Hrs.):

Basics fundamental of Mass Spectroscopy, interpretation of Mass spectra of simple compounds. Basics of IR spectroscopy. Interpretation of IR spectra of compound.

Unit-III (12 Hrs.):

Basic concepts and Instrumentation, recent trends in techniques and pharmaceutical application of HPLC and its various methods.
Adsorption, Partition, Reverse phase, chemically bonded phase, Ion exchange, Ionic-ion-pair, affinity, size exclusion and chiral chromatographic methods.

Unit-IV (12 Hrs.):

HPTLC: Detailed theory, instrumentation and applications.
Gas Chromatography: Detailed theory, instrumentation and applications.

Introduction of various thermal methods (TGA, DTA and DSC) - theories, instrumentation and applications.

Unit-V (12 Hrs.):

Electron microscopy, Scanning probe microscopy.
Electron diffraction, X-Ray diffraction methods.
Principle and application of Enzyme and Radio immunoassay techniques.

Books Recommended:

1. Willard, Merrit, Dean & Settle, Instrumental methods of analysis Van Nostrand.
2. Silverstein, spectrometric identification of organic compounds, Willey.
3. Beckett & Stenlake, Practical Pharmaceutical chemistry, CBS publisher, New Dehli.
4. Kemp William, Organic spectroscopy, Pal Grav, N. Y.
5. Kalsi P. S., Spectroscopy of organic compounds, New age publishers, New Delhi.
6. Hunson, J. W., ed. Pharmaceutical analysis, Modern methods part A & B, Marcel Dekker.
7. Sinder, Text book of HPLC.
8. Ewing: Instrumental methods of Chemical Analysis.

M.PHARM.-I SEMESTER : COMPULSORY (2013-14)
COURSE – II: PRODUCT DEVELOPMENT (THEORY)

Course Code : PHSC-1202

04hrs/week

Unit-I (12 Hrs):

Formulation Considerations -

Stability, solubility, pKa, dissolution rate, partition coefficient. In vitro and In-Vivo evaluation techniques, product formulation and C.G.M.P.

Designing of Pharmaceuticals -

Tablet formulation, Special tablets, preparation of components for compression, characterization of granulation, Coating of tablets, Evaluation of tablets, Equipments and processing problems in tablet.

Unit-II (12 Hrs):

Topical and rectal Absorption of drugs, formulations and evaluation.

Liquids –

Formulation considerations of oral liquids, Suspensions, emulsions, development of various products .

Formulation consideration of parenteral, ophthalmic, depot products, Large volume and Small volume Parenterals, Environmental control and quality assurance in parenteral drug manufacturing.

Unit-III (12 Hrs):

Introduction to Controlled and Novel Drug Delivery Systems,

Sustained release dosage forms, Prodrug concept, nanoparticles, liposomes, resealed erythrocytes, transdermal and other novel drug delivery systems.

Unit-IV(12 Hrs):

Packaging of Pharmaceuticals -

Stability in Pharmaceuticals and Study of stability kinetics.

Types of containers and closures, packaging and stability assessment.

Unit-V (12 Hrs):

Optimization techniques in Pharmaceutical Formulations and processing.

Pilot-plant and scale-up techniques

BOOKS RECOMMENDED: -

1. Lachmann, L., Lieberman, H.A. & Kanig, J.I.: The Theory and Practice of Industrial pharmacy. Lea and Fibiger, Philadelphia.
2. Banker, G.S. & Rhodes, C.T. : Modern Pharmaceutics, Marcel Dekker Inc. New York and Basel.
3. Turco, S. & King R.E. : Sterile Dosage Forms, Lea and Febiger, Philadelphia
4. Bean, H.S., Backett, A.H. & Carless, J.E: Advances in Pharmaceutical Sciences, Academic Press, London and Newyork.
5. Jain, N.K.: Controlled and Novel Drug Delivery , CBS, Delhi
6. Robinson, J.R. & Lee, V.H.L.: Controlled Drug Delivery, Marcel Dekker, New York and Basel.
7. Chien,Y.W.: Novel Drug Delivery Systems, Marcel Dekker,New York and Basel
8. Jain N. K. Pharmaceutical Product Development, CBS Publisher, Delhi

M.PHARM - I SEMESTER : COMPULSORY (2013-14)
COURSE-III: PHARMACEUTICAL BIOTECHNOLOGY (THEORY)

Course Code : PHSC-1203

04hrs/week

Unit-I (12 Hrs.):

Biotechnology: Introduction, terminologies used in biotechnology, role of biotechnology in industry. Pharmaceutical biotechnology and its future role in human care.

Enzymes: Classification and nomenclature, mode and mechanism of enzyme action. Pharmaceutical Applications of enzymes. Bacterial enzymes, industrial enzymes and production of enzymes. Study of Pharmaceutical and therapeutic enzyme.

Unit-II (12 Hrs.):

Immobilization: Various techniques, immobilization of cells and enzymes. Applications of Immobilization - enzyme and cell immobilization, its therapeutic applications.

Genetics: Structure of DNA as genetic material, Replication, repair, gene rearrangements, recombination and transposition, RNA synthesis and splicing. Protein synthesis and targeting. Control of gene expression in prokaryotes. Eukaryotic chromosomes and gene expressions.

Unit-III (12 Hrs.):

Recombinant DNA technology: Introduction, mutagenesis, cutting and rejoining. Polymerase chain reaction, Isolation and amplification of genes, gene expression genetic recombination: Transfer of characters, genetic recombination, phage crosses, and gene transfer mechanism.

Genetic disorders and gene therapy: Single gene disorders, its molecular genetics, common diseases, auto-immune diseases, cancer, cardiovascular diseases, nervous disorders. Gene therapy: current Gene therapy of genetic disorders like cystic fibrosis, Thalassaemia, Neuroblastoma, hepatitis, AIDS, diabetes, hemophilia B etc.

Unit-IV (12 Hrs.):

Immunology, Monoclonal antibodies and Hybridoma technology: A brief introduction to immunology. Formation and selection of hybrid cells, principles and productions of monoclonal antibodies, commercial production, characterisation, quality control and storage of monoclonal antibodies. Advantages and applications of monoclonal antibodies.

Immunomodulators: Principles of immunomodulation, source of immunomodulators, mode and mechanism of their action.

Unit-V (12 Hrs.):

New generation Vaccines : Overview of conventional vaccine, production (BCG, small pox, typhoid, cholera, polio etc.) preparation and standardization, Principles of multivalent subunit vaccines (ISCOMS, SMMA complexes etc.), synthetic peptide vaccines, recombinant antigen vaccines, vector vaccine, fertility vaccines, malaria vaccine, leprosy vaccine, transonic plant vaccines.

Tissue culture: Introduction, historical background, preparation of culture media, types of culture, modification through transformative cell culture, Regeneration of plants. Micropropagation, protoplast microinjection Methods of gene transfer in plants, pharmaceutical applications of plant tissue culture.

BOOKS RECOMMENDED:

1. Pharmaceutical Biotechnology: Vyas and Dixit.
2. Gene VII: Lewin Benjamin.
3. Industrial Microbiology: L.E. Casida.
4. Biotechnology- The Biological Principles: M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury.
5. Microbial Genetics: David Freifelder.
6. Immunology: J. Kubly.
7. Immunology: Weir.

M.PHARM. I SEMESTER (2013-14)
COURSE-IV: METHODS IN PHARMACEUTICAL RESEARCH (PRACTICAL)
Course Code : PHSC-1204 08hrs/week

Practicals:

Practical exercises based on the topic mentioned in theory syllabus.

Books recommended:

1. Willard, Merrit, Dean & Settle, Instrumental methods of analysis Van Nostrand.
2. Silverstein, spectrometric identification of organic compounds, Willey.
3. Beckett & Stenlake, Practical Pharmaceutical chemistry, CBS publisher, New Dehli.
4. Kemp William, Organic spectroscopy, Pal Grav, N. Y.
5. Kalsi P. S., Spectroscopy of organic compounds, New age publishers, New Delhi.
6. Hunson, J. W., ed. Pharmaceutical analysis, Modern methods part A & B, Marcel Dekker.
7. Sinder, Text book of HPLC.
8. Ewing: Instrumental methods of Chemical Analysis.

M.PHARM. I SEMESTER (2013-14)
COURSE-V: PRODUCT DEVELOPMENT (PRACTICAL)

Course Code : PHSC-1205

08hrs/week

Experiments based on following concepts:

1. Formulation development of compressed tablets.
2. Formulation development of topical preparations.
3. Formulation development of oral liquids.
4. Formulation development of stable suspensions and dry suspensions.
5. Formulation development of emulsions.
6. Formulation development of small volume parenterals.
7. Formulation development of ophthalmic preparations.
8. Assessment of stability studies according to ICH guidelines.
9. Evaluation of packaging materials.
10. Product development of sustained release dosage forms.

M.PHARM. I SEMESTER (2013-14)
COURSE-VI: PHARMACEUTICAL BIOTECHNOLOGY (PRACTICAL)
Course Code : PHSC-1206 08hrs/week

Practical exercises based on the topics mentioned in theory syllabus

BOOKS RECOMMENDED:

1. Pharmaceutical Biotechnology: Vyas and Dixit.
2. Gene VII: Lewin Benzamin.
3. Industrial Microbiology: L.E. Casida.
4. Biotechnology- The Biological Principles: M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury.
5. Microbial Genetics: David Freifelder.
6. Immunology: J. Kuby.
7. Immunology: Weir.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP (2013-14)

COURSE - I: ADVANCED PHARMACEUTICS (THEORY)

Course Code : PHSC-2201

04hrs/week

Unit-I (12 Hrs.):

Recent advances in Tablet technology. Parenteral technology and Microencapsulation.

Process automation in pharmaceutical manufacturing, role of GMP, Quality assurance and validation.

Unit-II (12 Hrs.):

Formulation development of vitamin and antibiotics products.

Disperse systems- Molecular dispersion, solubilization theory, Methods of solubility enhancement, factors influencing solubility.

Unit-III (12 Hrs.):

Coarse dispersions- Physical stability of suspensions and emulsion, role of zeta potential in stability of coarse dispersions, theory of emulsification, micro and multiple emulsions, rheology of suspensions and emulsions. Drug kinetics in coarse disperse systems, drug diffusion in coarse dispersion systems.

Unit-IV (12 Hrs.):

Stability indicating assays.

Advances in pharmaceutical packaging.

Advances in Polymer sciences and its applications in pharmacy.

Unit-V (12 Hrs.):

Radiopharmaceuticals - production, control and its applications.

Collection and classification of experimental data and its statistical treatment, Probability- definition and laws of probability, Regression and correlation, method of least squares, correlation coefficient and multiple regression, Test of significance and t - test, Statistical quality control, process control, control chart, acceptance sampling plans.

BOOKS RECOMMENDED:

1. Liberman , H.A. & Lachman, L., Pharmaceutical Dosages Forms: Tablets. Vol. I,II and III.
2. Avis, Lachman I. & Liberman H.A.: Pharmaceutical Dosages Forms: Parenteral Medication Vol. I and II.
3. Turco, S. and King, R.F., Sterile Dosages Forms., Lea and Febiger, Philadelphia.
4. Remington's Pharmaceutical Sciences.
5. Martin, A.N., Swarbrick, J & Cammarata, A., Physical Pharmacy, Lea and Febiger, Philadelphia.
6. Carstensen, J.T. Theory of Pharmaceutical Systems, Academic Press, New York and London.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP (2013-14)
COURSE - II: BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)
Course Code : PHSC-2202 04hrs/week

Unit-I (12 Hrs.):

Transport of drugs through membranes and barriers other than GI Tract.

Buccal absorption, salivary excretion of drugs, excretion of drugs via sweat, excretion of drugs into milk, penetration of drugs into eye, transfer across placenta, passage of drugs into and out of cerebrospinal and brain.

Measurement and Interpretation of in vitro Rates of Dissolution. Intrinsic rates of dissolution, dissolution of drugs from solid dosage forms, various modern methods and models for testing dissolution rate, factors and kinetics of dissolution.

Unit-II (12 Hrs.):

Bioavailability and bioequivalence

Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence.

Correlation of in vitro dissolution & in vivo bioavailability.

Statistical concepts in estimation of bioavailability and bioequivalence.

Kinetics of reversible pharmacological effects - direct and indirect effects.

Unit-III (12 Hrs.):

Pharmacokinetics:-

Consideration of one, two and multiple compartment models on intravenous administration, intravenous infusion and first order absorption of single dose.

Kinetic of multiple dosing:- dosage regimens, loading and maintenance doses, one and two compartment models on intravenous administration, and first order absorption of single dosing.

Unit-IV (12 Hrs.):

Clinical Pharmacokinetics Concept, absorption, distribution and renal clearance and elimination, Disposition and absorption kinetics, intravenous dose, constant i.v. infusion, extravascular dose, metabolite kinetics.

Therapeutic regimens- therapeutic response and toxicity, Dosage regimens, Clinical trial studies.

Unit-V (12 Hrs.):

Physiologic Pharmacokinetic Models

Concepts, physiologic pharmacokinetic models with binding blood flow - limited versus diffusion - limited model, applications and limitation of physiologic pharmacokinetic models, Mean Residence Time (MRT), Statistical Moments Theory, Mean Absorption Time (MAT), Mean Dissolution Time (MDT).

Non-Linear Pharmacokinetics -

Recognition of non-linearity, one and two compartment open model with Michaelis-Menton kinetics, determination of K_m and V_m , non-linear tissue binding constants.

BOOKS RECOMMENDED:-

1. Gibaldi M., Pharmacokinetics, Marcel Dekker Inc. New York.
2. Abdou, H.M. Dissolution, Bioavailability and Bioequivalence, Mack Publishing Co. Easton, PA
3. Smith, R.V. & Stewart, J.T., Text book of Biopharmaceutical Analysis, Lea and Febiger, Philadelphia.
4. Wagner J.G.- Fundamentals of Clinical Pharmacokinetics, Drug Intelligence Pub. Hamilton.
5. Welling, P.G., Tse, F.I.S. & Dighe, S.V.(eds), Pharmaceutical Bioequivalence, Marcel Dekker Inc., New York
6. Gibaldi, M., Perrier, D.: Pharmacokinetics, Marcel Dekker Inc., New York
7. Rowland, M. & Tozer, T. N., Clinical Pharmacokinetics - Concept and Applications, Lea and Febiger USA.
8. Shargel, L. & Yu, A.B.C.: Applied Biopharmaceutics & Pharmacokinetics, Appleton and Lange, Connecticut, USA.
9. Hotari, R.E., Biopharmaceutics and clinical pharmacokinetics, Marcel Dekker Inc., New York and Basel.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP (2013-14)
COURSE - III: CONTROLLED AND NOVEL DRUG DELIVERY SYSTEMS (THEORY)
Course Code : PHSC-2203 04hrs/week

Unit-I (12 Hrs.):

Fundamentals of Controlled Release Drug Delivery Influence of drug properties and routes of drug administration on the design of sustained and controlled release systems.

Pharmacokinetic/Pharmacodynamic basis of drug delivery. Dosing considerations and bioavailability assessment. Regulatory assesment.

Unit-I (12 Hrs.):

Design and Fabrication of:

- Oral controlled release drug delivery systems.
- Parentral products.
- Implantable products.

Unit-III (12 Hrs.):

- Transdermal therapeutic system.
- Prodrugs as sustained chemical delivery systems.

Biochemical and Molecular Approach to Controlled Drug Delivery-

- Liposomes
- Niosomes

Unit-IV (12 Hrs.):

- Microspheres
- Resealed erythrocytes
- Nanoparticles
- Osmotic pumps

Unit-V (12 Hrs.):

Targeted Drug Delivery

Definition,concept,target-drug interactions, delivery systems.

Advances in Controlled and Novel Drug Delivery.

BOOK RECOMMENDED:

1. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York and Basel.
2. Jain, N.K.: Controlled and Novel Drug Delivery,CBS, New Delhi.
3. Jain,N.K.Advances in Novel and Controlled Drug Delivery.
4. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York and Basel.
4. Roseman, T.J.: Controlled Release Drug Delivery Ssytems, Marcel Dekker New York
5. Goldberg : Targeted Drugs.
6. Bruck, S.D., Controlled Drug Delivery , Vol. I & II.
7. Juliano, R.L. : Drug Delivery Systems.
8. Review articles published in various journals.
9. Jain, N.K.: Progress in Controlled and Novel Drug Delivery, CBS Publisher, New Delhi.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP (2013-14)
COURSE - IV: ADVANCED PHARMACEUTICS (PRACTICAL)
Course Code : PHSC-2204

16hrs/week

(A) Advanced Pharmaceutics

1. Experiments based on microencapsulation.
2. Formulation development of vitamins & antibiotics.
3. Experiments based on solubility enhancement.
4. Preparation & evaluation of micro and multiple emulsions
5. Experiments based on rheological & thermal characterization of polymers.

(B) Biopharmaceutics and Pharmacokinetics

6. Experiments based on dissolution studies of solid dosage forms.
7. Experiments based on bioavailability and bioequivalence determination
8. Experiments based on *in vitro* dissolution and *in vivo* correlation.
9. Experiments based on pharmacokinetic parameter determination after single dose administration using compartment modeling and non-compartment modeling.
10. Experiments based on buccal absorption and salivary excretion of drugs.

(C) Novel Drug Delivery System (NDDS)

11. Formulation design of liposomes, niosomes, microspheres, microcapsules, sustained & controlled drug delivery systems and resealed erythrocytes.
12. Preparation and characterization of transdermal drug delivery systems.
13. Preparation and characterization of osmotic pumps.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP (2013-14)
(COMPULSORY PAPER FOR ALL SPECIALIZATIONS)
COURSE - V: DRA, INTELLECTUAL PROPERTY RIGHTS AND QUALITY
ASSURANCE(THEORY)

Course Code : PHSC-2205

4hrs/week

Unit-I (12 Hrs.):

Requirements of GMP, cGMP, GLP, USFDA, WHO Guidelines and ISO 9000 Series.

Drugs and Cosmetics Acts and rules, Drug Regulatory Affairs.

Documentation- Protocols, Forms and Maintenance of records in Pharmaceutical industry.

Unit-II (12 Hrs.):

Preparation of documents for New Drug Approval and Export Registration.

Processing and its application, Intellectual Property Rights (Patent, Copyright and Trademarks).

Sewage disposal and pollution control

Unit-III (12 Hrs.):

Concepts in Validation, Validation of manufacturing, Analytical and Process Validation and its Application

Basic concepts of Quality Control and Quality Assurance Systems, Source and Control of Quality Variation of Raw Materials: Containers, Closures, Personnel, Environmental, Etc.

Unit-IV (12 Hrs.):

In-process quality tests, IPQC problems in Pharmaceutical industries. ICH Guidelines.

Unit-V (12 Hrs.):

Sampling Plans, Sampling and Characteristic Curves.

Master Formula generation and Maintenance, Standard Operating Procedure (SOP) for different dosage forms.

Books and References Recommended

1. Willing, S.H., "Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc., New York
2. Drugs and Cosmetics Acts and rules
3. Patel, A.H., "Industrial Microbiology" Macmillon India Ltd., Delhi.
4. Nash, R.A. and Wachter A.H., "Pharmaceutical Process Validation" Marcel Dekker, Inc., New York
5. Bolton, S.H. "Pharmaceutical Statistics"
6. Banker, G.S. and Rhodes, C.T. "Modern Pharmaceuticals" Marcel Dekker, Inc., New York.
7. Careleton, F.J. and Agallow, J.P. "Validation of Aseptic Pharmaceutical Processes" Marcel Dekker, Inc., New York.
8. Garfeild "Quality Assurance Principles of Analytical Laboratories"
9. Latest Editions of I.P., U.S.P and B.P.

M.PHARM. II SEMESTER: PHARMACEUTICAL CHEMISTRY GROUP (2013-14)

COURSE - I: DRUG DESIGN AND DISCOVERY (THEORY)

Course Code: PHSC-2207

4hrs/week

Unit-I (12 Hrs.):

1. Introduction to Drug design and discovery: Historical perspective, generation of leads and lead optimization, objective of lead optimization, analog approach, cell biology and genomics as a source of drugs, future development in the drug design
2. Molecular Recognition in drug design: Introduction, thermodynamic considerations for drug design. Physical basis of intermolecular interactions, total energy intermolecular interaction, estimating individual group components in ligand receptor interactions and co-operativity and thumb rules.

Unit-II (12 Hrs.):

3. Stereochemistry and drug design: Stereospecificity in molecular recognition, significance of stereochemistry in drug design, methods of obtaining pure stereoisomer.
4. Bioisosterism in drug design:
5. Three dimensional aided drug design: structure aided drug design process, methods to derive 3D structure. Design process, softwares aided drug design, optimization of identified compounds, examples of structure aided drug design

Unit-III (12 Hrs.):

6. Computer aided drug design: Pharmacophoric approach, Pharmacophore based ligand design, Pharmacophore concept, Pharmacophore elements and representation, active conformation, molecular superimposition, receptor excluded and receptor essential volumes, salvation effects, examples of 3D Pharmacophore models and their uses.
7. QSAR: Fundamentals of QSAR, biological data, the additivity of group contribution, Hansch analysis and related approaches, physicochemical properties, statistical methods in QSAR, application of Hansch and related approaches, 3D QSAR approach.
8. Molecular modeling: generation of 3D coordinates, sketch approach, conversion of 2D structures in 3D form, force fields, geometry optimization, energy minimization procedures. Quantum mechanical methods, conformational analysis, Pharmacophore identification, molecular modeling in 3D QSAR-CoMFA and related approaches.

Unit-IV (12 Hrs.):

9. Nucleic acid based drug design: structure, protein-nucleic acid and drug-nucleic acid interaction
10. Prodrug and metabolite considerations in Prodrug design: Aims of prodrug designing. Types of prodrugs, fundamental groups involved in prodrug designing. Bioprecursors prodrugs.
11. Retrometabolism based drug design and targeting.

Unit-V (12 Hrs.):

12. High throughput screening for lead discovery
13. Combinatorial chemistry including solid state. parallel & liquid phase, synthesis , identification of hits & concept of deconvolution.

Books Recommended:

1. Burger, A., Med. Chem.
2. Wilson and Gisvold, Organic Med. Pharmaceutical Chem.
3. Ariens, Drug Design, Academic press, NY,1975.
4. Schueler, Chemobiodynamic and Drug Design
5. Foye, Principals of Med. Chem.
6. Martin, Y., QSAR, 1978
7. Hansch, Principles of Med. Chem.
8. Kubiny's, QSAR
9. Holtje. Sippl., Rognan and Folkers, Molecular Modeling.
10. P.K. Larsen, Tommy and U.Madsen, textbook of Drug Design and Discovery.
11. T.J. Perun and C.L. Propst, Computer Aided Drug Design.

M.PHARM. II SEMESTER: PHARMACEUTICAL CHEMISTRY GROUP (2013-14)
COURSE - II: ADVANCES IN MEDICINAL CHEMISTRY (THEORY)
Course Code : PHSC-2208 4hrs/week

Incorporating latest advances, the following topics would be dealt:

Unit – I (12 Hrs.):

Chemistry of cell membrane

Receptor, drug receptor interaction, G- protein coupled receptors, ion channel linked receptors, ligand gated ion channels (LGICS).

Chemical contraceptives (latest advances).

Unit – II (12 Hrs.):

Rational design of enzyme inhibitors.

- a. Design of non – covalently binding enzymes inhibitors, rapid reversible inhibitors, slow, tight & slow tight inhibitors, transition state analogs, multisubstrate inhibitors.
- b. Current development with respect to the inhibition of the following enzymes, reverse transcriptase, catechol-*o*-methyl transferase, ACE, glycylamide ribonucleotide transformylase, HMG Co A reductase inhibitors, antimetabolites, dihydrofolate reductase inhibitors, PDE, protein kinase.
- c. Design of covalently binding enzyme inhibitors, mechanism based inhibitors, affinity labels, pseudoreversible inhibitors. One representative example each from pyridoxyl phosphate dependent enzyme, Gaba transferases, ornithine decarboxylase, MAO, Thymidylate synthase, creatine kinase and B- glucosidase inhibitors.

Unit – III (12 Hrs.):

Nitric oxide: second messenger, introduction chemical properties of nitric oxide, reaction of nitric oxide with metals, interplay between the reactions of nitric oxide in biological system, nitric oxide synthetase isoenzymes, nitric oxide synthetase inhibitors, cytotoxic role of nitric oxide, therapeutic significance of NOS inhibitors & nitric oxide.

Endorphins: discovery of enkephalins and endorphins latest development.

Antidiabetics(latest advances)

Unit – IV (12 Hrs.):

Advances in medicinal chemistry of cardiovascular, anti arrhythmics, anti anginal, antihypertensive and anti-hyperlipidemics.

prostaglandin and other eicosanoids: nomenclature, SAR, metabolism.

Unit – V (12 Hrs.):

Antineoplastics agents: molecular mechanism of cancer, oncogenes, DNA Intercalating agents, strand breakers.

Anti viral agent: DNA & RNA viruses, retro viruses, Strategies to design Anti HIV drugs, viral replication, development of new drugs & drug discovery(2DV, 3TC, ABC, D4T).

Books Recommended:

- 1 Foye W, "Principles of Medicinal Chemistry" Lea & Febiger.
- 2 Delgado J.N., Remers WA eds, "Wilson & Giswolds Text Book of organic Medicinal & Pharmaceutical chemistry" Lippincott, New York.
- 3 Monographs and relevant review articles appearing in various periodicals and journals.
- 4 Alex Gringauz-"Introduction to Medicinal Chemistry" Wiley-VCH, Inc. New York.
- 5 Abraham DJ,ed., Burger's Medicinal Chemistry & Drug Discovery, Vol-I-VI, John Wiley & sons, New Jersey.

M.PHARM. II SEMESTER: PHARMACEUTICAL CHEMISTRY GROUP (2013-14)
COURSE - III: ADVANCES IN ORGANIC CHEMISTRY (THEORY)

Course Code : PHSC-2209

4hrs/week

Unit – I (12 Hrs.):

Concept of aromaticity involving ring systems & aromaticity, hydrogen bonding & other weaker bondings, EDA complexes, crown ethers and inclusion compounds.

Bronsted and Lewis concepts, acidic and basic catalysis, hard and soft acids & bases. Effect of structure on the strength of acids & bases. Effect of medium on acidic & basic strength.

Unit – II (12 Hrs.):

Stereochemistry: Elements of symmetry

Kinds of molecules displaying optical activity, compounds with chiral carbon atom, compound with other quadrivalent chiral atoms, compound with trivalent chiral atoms, optical isomerism in compounds containing no chiral atom: biphenyls, allenes, compounds with exocyclic double bonds, spirans, chirality due to helical shape, chirality caused by restricted rotation of other types, cis trans isomerism resulting from double bonds, monocyclic compounds, fused ring systems, chirality and importance of chiral drugs.

Unit – III (12 Hrs.):

Carbanion chemistry:

Generation of carbanions by deprotonation and other means of generating enolates. Alkylation of enolates, oxygen versus carbon as the site of alkylation, alkylation of aldehydes, ester, amides, & nitrile. The nitrogen analogs of enols & enolate enamines and imine anions.

Elimination reactions:

E2, E1 & E1cb mechanisms, orientation effect in elimination reactions, stereochemistry of E2 reaction, elimination not involving C-H bond.

Unit – IV (12 Hrs.):

Reactive intermediates: carbocations, carbonions, carbenes, nitrenes, &

Free radicals: stability and reactivity of these intermediates.

Rearrangements :

Detailed knowledge of rearrangement reactions involving rearrangement to electron deficient carbon and nitrogen, oxygen; inter & intra molecular aromatic rearrangements, mixed type of aromatic rearrangement.

Unit – V (12 Hrs.):

Synthetic strategies:

Protection & deprotection of various groups, disconnection approach, Synthons for carbon-carbon bond formation, difunctional compounds, selective functional group interconversion (FGI), retrosynthetic analysis, synthetic approaches for attaching heterocyclic ring system in drug molecule having two and six members hetero aromatic rings, fused ring systems.

Books Recommended:

- 1) J. March, Advanced organic chemistry, reactions mechanism and structures, John Wiley and Sons, New York latest edition.
- 2) Eliel, I. Erenest and Sammel H, Stereochemistry of organic compounds, John Wiley & Sons New York.
- 3) Francis, A.C and Richard J.S, Advanced organic chemistry, 3rd edition, Reaction & Synthesis, Plenum Press, New York.
- 4) Iyer R.P., Ghone S.A, Degani M.S., Mohanraj K. and Jain N., Synthesis of drug, vol I, Sevak Publications P. Ltd, Mumbai, 2008.
- 5) Monographs & relevant review articles appearing in various periodicals & journals.

M.PHARM. II SEMESTER: PHARMACEUTICAL CHEMISTRY GROUP (2013-14)
COURSE - IV: ADVANCED PHARMACEUTICAL CHEMISTRY (PRACTICAL)
Course Code : PHSC-2210 **16hrs/week**

Practical exercises based on the topics mentioned in theory syllabus of:

- i. Drug Design and Discovery
- ii. Advances in Medicinal Chemistry
- iii. Advances in Organic Chemistry.

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP (2013-14)
COURSE - I: NATURAL PRODUCTS (THEORY)
Course Code : PHSC-2212 **04hrs/week**

Unit –I (12 Hrs):

Methods of study of biosynthetic pathways; such as tracer technique and auto radiography.

General biosynthetic studies of alkaloids of pharmaceutical significance of pyridine, piper dine, tropane, quinoline, isoquinoline, indole and phenthrope groups. Biosynthesis of steroids, cardiac glycosides, flavanoids, coumarins.

Unit-II (12 Hrs):

Distribution, detection, extraction, isolation and evaluation of vinca, opium, ergot, rauwolfia, cinchona, digitalis, senna, Dioscorea, glycyrrhiza, podophyllum, taxus, guggul and artenusia. Detailed and comparative studies of chemical constituents of drugs mentioned above is expected.

Unit-III (12 Hrs):

Screening of drugs for pharmacological activity - Protocols and screening methods for anti-diabetic, anti inflammatory, antihepatotoxic, antifertility and diuretic activities.

Unit-IV (12 Hrs):

An overview of current status of plants used as anticancer, antihepatotoxic, antimalarial, antihypertensive and hypolipidemic and adaptogenic agents. Important drugs affecting C.N.S. system.

Unit-V (12 Hrs):

Herbs and Health foods, Herbal cosmetics, Aromatherapy, Plants used in alternative system of medicine.

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP (2013-14)
COURSE - II: ADVANCED PHARMACOGNOSY (THEORY)
Course Code : PHSC-2213 **04hrs/week**

Unit-I (12 Hrs):

Quantitative microscopy as applied to drug evaluation principles and procedures of microtome sectioning and staining procedures, preparation of biological material & for examination by electron microscopy

Unit-II (12 Hrs):

Microchemical tests as applied to crude drugs and their constituents, Fluorescence analysis in evaluation of drugs.

Unit-III (12 Hrs):

Phytochemical Methods: -

Analytical procedures and screening of vegetable materials for phenolic compounds, terpenoids, organic acids, lipids and related compounds, nitrogen compounds, sugars and their derivatives & macro-molecules.

Unit -IV (12 Hrs):

A study of history and development of taxonomy and chemotaxonomy. Artificial and natural systems of classification . Principles of classification . Rules of plant nomenclature and modern trends in taxonomy. Study of important families of medicinal and phylogenetic importance.

Unit-V (12 Hrs):

Chemical constituents as taxonomic character and Application of comparative phytochemistry with regards to alkaloids, glycosides, terpenoids, flavanoids and other pigments, Lipids, acetylenic and sulphur compounds.

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP (2013-14)
COURSE - III: PLANT BIOTECHNOLOGY (THEORY)
Course Code : PHSC-2214 **04hrs/week**

Unit-I (12 Hrs):

Plant tissue Culture: Historical perspectives, Types and techniques. Organogenesis and embryogenesis, micro propagation of medicinal and aromatic plants. Nutritional requirement of tissue culture, culture media, growth and metabolism of plant tissue culture. Growth parameters of callus and cell culture.

Unit-II (12 Hrs):

Secondary metabolism in tissue cultures and production of pharmaceuticals. Role of plant growth regulators in tissue culture.

Biochemical conversions -Application of plant cell cultures and micro-organisms. Abberant synthesis.

Unit-III (12 Hrs):

Protoplast culture: isolation of protoplast & Haploid protoplast, protoplast fusion and its scope in quality improvement of drug plants. Germ plasm storage cell immobilization, properties and biosynthetic potential of immobilized systems.

Cryopreservation and retention of biosynthetic potential in cell cultures.

Unit-IV (12 Hrs):

Genetic engineering with special reference to plant cells and micro-organisms. Mutation, Hybridization and diploides chemodems and artificial prod. of mutations.

Unit-V (12 Hrs):

Culture Aspects- Variability in drug activity . Review of exogenous and endogenous factor and in drug production . Soil and plant growth, plant nutrition and their role in drug production

Recent studies on production of mentha, lemongrass, Cinchona, Vinca, ergot, solanaceous drugs and steroidal precursor.

Phytogeograpy and phytogeographical distribution of medicinal plants with special reference to India.

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP (2013-14)
COURSE - IV: ADVANCED PHARMACOGNOSY (PRACTICAL)
Course Code : PHSC-2215 **16hrs/week**

Practical exercises based on the topics mentioned in theory syllabus of

- (I) Natural Products
- (II) Advanced Pharmacognosy
- (III) Plant Biotechnology

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP (2013-14)
COURSE – I: ADVANCED BIOTECHNOLOGY (THEORY)
Course Code : PHSC-2217 **04hrs/week**

Unit-I (12 Hrs.):

IMMUNOLOGY: Principles of disease and epidemiology : Pathology and classification of infectious diseases, spread of infection. Mechanism of pathogenicity. Non-specific and specific defense mechanism of the host. Cells and organs of immune system. Humoral & Cell-mediated immunity, Natural immunity, Immune memory, immune tolerance.

Antigens, Immunoglobulin classes, structure and their function. B-cells receptor, B-cell maturation, activation and differentiation, T-cell receptor, its maturation, activation and differentiation. MHC and immune responsiveness. Antigen processing and presentation. Immune effector mechanism: Cytokines, The complement system, Inflammation & leukocyte migration. Cell mediated and humoral effector responses. Hypersensitive reactions, immunosuppression, autoimmune disorders, its molecular mechanism, immunodeficiency disorders, tumour immunology.

Unit-II (12 Hrs.):

IMMUNOMODULATORS: Principle of immunomodulation, source of immunomodulators, mode & mechanism of their action, non-classical techniques of immune modulators, preparation & therapeutic applications of immunomodulators.

IMMUNOTECHNOLOGY: Antigen-antibody reaction, basics of immunoassays, immunoprecipitation-agglutination and complement fixation, isotopic and non-isotopic immunoassays.

Assessment of cell mediated immunity- Purification and bioassay of IL-1 and IL-2, cytotoxicity assays, etc. Microscopic techniques for subcellular location of antigen and diagnosis. Electron microscopy, avidin-biotin systems, gold labelling.

Immunofluorescence, cell separation techniques, immunosensors and Nucleic acid based diagnostics.

Unit-III (12 Hrs.)

IMMOBILIZATION: Introduction, methods of immobilization, selection of methods, entrapment and encapsulation, characterisation, kinetics of immobilized biocatalysts, immobilized cells and application.

Potentials of immobilized bioactives.

MONOCLONAL ANTIBODIES AND HYBRIDOMA TECHNOLOGY: Introduction, Antibody structure and class, function, Principles of monoclonal antibody production. Advantages and limitations. Human hybridomas, Applications of monoclonal antibodies.

Unit-IV (12 Hrs.):

VACCINE PRODUCTION AND QUALITY CONTROL: Vaccines introduction, conventional vaccines (BCG, small pox, typhoid, cholera, polio, etc.) preparation and standardization.

NOVEL VACCINES: Multivalent subunit vaccines. Le. ISCaMs and SMMA complexes, synthetic peptide vaccines, recombinant antigen vaccines, vector vaccines, recombinant HBV, influenza vaccine, fertility control vaccines, malaria vaccine, development of AIDS vaccine. New combined vaccines. Use of carrier systems like liposomes, microspheres, nanoparticles, as adjuvants in immunization. Transgenic plant vaccine.

Unit-V (12 Hrs.):

MOLECULAR APPROACHES TO DRUG DELIVERY SYSTEM DESIGN: Ligand mediated endocytosis, ligand anchoring and designing of colloidal drug delivery systems

DRUG DELIVERY ASPECTS OF BIOTECHNOLOGY PRODUCTS: Introduction to drug delivery systems, their targeting potentials, various delivery systems used for delivery of biotechnological products (Liposomes, microspheres, nanoparticles, immobilization techniques, etc.). Physicochemical and Physiologic considerations and their significance.

PRACTICAL BASED ON THEORY

BOOKS RECOMMENDED:

Biotechnology - The Biological Principles: M D Trevan, S Boffey, K H Goulding and P Stanbury

Pharmaceutical Biotechnology, S. P. Vyas and V. K. Dixit

Immobilization of Cells and Enzymes: Hosevear kennady cabral & Bicker staff

General Microbiology: RY Stainer

Essential and applications of microbiology: Judy Kanda!

Microbiology: Pelczar, Reid and Chan

Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S Lawrence, Paul Matsudaira, James Darnell.

Virology: Fields

Therapeutic Peptides and Proteins: Formulation, processing and delivery systems: Ajay K Banga

Modern Biotechnology: S. B. Primrose

Immunology: IWeir

Immunology: Ivan Roitt, Johnathan Bronstoff, David Male

Medical Microbiology: Mackie and MacCartney

Diagnostic Procedures for Viral and Reckettsial Diseases: Lennett & Schmidt

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP (2013-14)
COURSE –II: MOLECULAR BIOLOGY AND GENETIC ENGINEERING (THEORY)
Course Code : PHSC-2218 **04hrs/week**

Unit-I (12 Hrs.):

Cell & Molecular Biology

Origin & evolution of life: Origin of micro and macromolecules and self assembled systems. Protenoid early systems. Laboratory simulation. Evolution of organisms molecules and genetic code.

Cell and its components, plasma membrane its structure and functions, The nucleus, cell growth and division, molecular organisation and behaviour of the genome.

Unit-II (12 Hrs.):

Cell motility and excitation, cell differentiation. Molecular basis of mutations. Biology and pathophysiology of cancer, diabetes, Thalessemia, cystic fibrosis, Hemophilia & other diseases-Physiological manifestations and symptoms.

PLANT CELL BIOLOGY: General structure and constituents of plant cells, cell wall organisation, synthesis assembly and turn over of cell wall components, cell surface related functions, adhesion, cell-cell interactions and other communications, transport, excretion, mitosis and miosis. Intracellular membrane endoplasmic reticulum and nuclear envelope.

Unit-III (12 Hrs.):

MOLECULAR GENETICS: Introduction to genetics, structure of DNA, DNA replication and transcription, enzymes involved in replication, isolation of DNA, RNA, etc. Gene sequencing and mutation.

GENE REGULATION AND EXPRESSION: Regulation of gene activity in prokaryotes and eukaryotes. Principles of regulation, E. coil lactose system, tryptophan operon, autoregulation, feed back inhibition, gene family, gene amplification, regulation of transcription and processing, translational control, gene rearrangement.

TECHNIQUES OF GENE ANALYSIS: Southern blotting, Northern and Western blotting, gene probes.

Unit-IV (12 Hrs.):

GENETIC DISORDERS: Single gene disorders and molecular pathology, molecular genetics and common diseases. autoimmune diseases, cancer, cardiovascular diseases, nervous disorder.

GENE THERAPY: Current methods of treatment of genetic disorders.

Future trends in treatment of genetic disorders, Gene replacement or corrective therapy, Targeting aspects.

Viral and non-viral gene therapy.

Gene therapy of genetic disorders like cystic fibrosis, Thalassaemia, Neuroblastoma, Hepatitis, AIDS, Diabetes.

Hemophilia Band SCID

Unit-V (12 Hrs.):

GENETIC ENGINEERING: Introduction, mutagenesis, cutting and rejoining. Polymerase chain reaction

Isolation and amplification of genes, gene expression and general introduction to genomics.

Genetic recombination: Transfer of characters, genetic recombination, phage crosses, gene transfer Mechanisms, plasmids, insertion of phage chromosomes, transduction, transformation.

Gene cloning: Cloning vectors, cloning techniques, cloning strategies, Cloning of eukaryote gene

Therapeutic protein expression, Transgenic animals, engineered gene expression, second generation protein program design, examples of engineered proteins of therapeutic potential. Applications of recombinant DNA technology.

PRACTICAL BASED ON THEORY

BOOKS RECOMMENDED:

1. Genetics. of Antibiotics Producing Microorganisms: G Sermonti
2. Principles of Gene Manipulation: R W Old and S B Primrose
3. Genes V and VI: Lewin Benjamin
4. Biochemical Engineering: F C Webb.
5. Biochemical Engineering: R Steel
6. Immunoassays - Daniel W Chan and Marie T Perlstein
7. Pharmaceutical Biotechnology, S. P. Vyas and V. K. Dixit
8. Gene Transfer and Expression Protocols - Methods in molecular biology, Vol VII, E T Murray (ed.).
9. Current Protocols in Molecular Biology, Vol. I and II: F M Asubel, John Wiley Publishers
10. Current Protocols in Cellular Biology, Vol. I and II, John Wiley Publishers.
11. Biological Reaction Engineering: I J Dunn, E Heinzle, J Ingham, J E Prenosil

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP (2013-14)
COURSE – III: INDUSTRIAL BIOTECHNOLOGY (THEORY)
Course Code : PHSC-2219 **04hrs/week**

Unit-I (12 Hrs.):

Enzyme Technology Process

Chemically and genetically modified enzyme. Isolation, purification and modification in enzymes. Enzymes as therapeutics, enzymes in drug delivery design.

Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach.

Unit-II (12 Hrs.):

DESIGN AND CONSTRUCTION OF FERMENTERS AND BIOREACTORS

Detailed study of the design and operation of different types of fermenters, ancillary fittings, transfer of spore suspension, transfer of inoculum from seed tank to fermenter, impeller design and agitator power requirements, measurement and control of dissolved oxygen, carbon-di-oxide, temperature, pH and foam.

Aeration, agitation and mass transfer in fermentation, Supply of air cleaning and sterilization of air, methods of providing air, air compression and air sterilization methods.

Types of bioreactors, modelling of immobilized biocatalyst reactors, bioreactors applications.

Unit-III (12 Hrs.):

FERMENTATION TECHNOLOGY

Media, solid state and liquid phase fermentation, surface culture, submerged and batch culture, continuous fermentation. Strain improvement.

Industrial fermentation of alcohol, citric acid, antibiotics, enzymes, vitamins, dextran, starch, alcohol and prostaglandins.

Yeast and its production. Production of single cell proteins

Unit-IV (12 Hrs.):

PRINCIPLES OF CELL CULTURE & PREPARATION TECHNIQUES

Preparation of tissue culture media, sterilization of plant materials, plant cell culture, isolation of single cells from intact plant. Growth determination and medium analysis. Hormonal control of growth. Initiation and maintenance of callus cultures.

APPLICATIONS OF CELL CULTURE TECHNIQUES

Cell isolation, in vitro cellular uptake studies, cell biochemistry study, secondary metabolite production, fermentation & genetic manipulation. Embryogenesis, embryo cloning, cell cloning prospects and perspectives. Therapeutic novel molecular expression, Trait improvement.

Unit-V (12 Hrs.):

PLANT AND ANIMAL CELL CULTURE

Types of cultures: Callus culture, Meristem-tip culture, organ culture (Flower and fruit organ culture), microspore and anther culture, protoplast culture, primary culture, continuous culture, cell fusion micropropagation

Modification through transformative cell culture, Ti-plasmids.

Regeneration of plants. Production of secondary metabolites. Protoplast microinjection. Mutagenesis technique in plant tissue culture.

Pest resistance, herbicide tolerance, peptidal hormones, production and applications.

PRACTICAL BASED ON THEORY

BOOKS RECOMMENDED

1. Industrial Biotechnology: L E Casida
2. Industrial Biotechnology: B M Miller and W Litsky
3. Microbial Technology Vols j & II: H Peppler
4. Industrial Biotechnology: Vedpal S Malik and Padma Sridhar
5. Biochemistry of Industrial Microorganisms: C Rainbow and A H Rose
6. Animal Cell Culture: Ian Freshney
7. Microbial Genetics: David Freifelder
8. Biochemical Engineering Fundamentals: Bailey and Ollis
9. Biotechnology of Antibiotics and Other Bioactive Microbial Metabolites: Giancarlo Lancini and Roland Lorenzetti
10. Bioreactor Design and Product Yield: Butterworth and Heinemann
11. Enzyme Assays - A Practical Approach: Robert Eisenthal and Michael J Danson
12. Fermentation and Biochemical Engineering Handbook: Henry C Vogel

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP (2013-14)
COURSE – IV: PHARMACEUTICAL BIOTECHNOLOGY (PRACTICAL)
Course Code : PHSC-2220 **16hrs/week**

Practical exercises based on the topics mentioned in theory syllabus of

- (I) Advanced Biotechnology
- (II) Molecular biology and Genetic Engineering
- (III) Industrial Biotechnology

M.PHARM. III SEMESTER: SESSION (2013-14)
COURSE – ELECTIVE – I : COSMETICOLOGY (THEORY)
Course Code : PHSE-3201 03hrs/week

Unit-I (09 Hrs.):

1. Physiological consideration: Skin, hair, nail and eye - in relation to cosmetic application.
2. Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

Unit-II (09 Hrs.):

3. Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics

Unit-III (09 Hrs.):

4. Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

Unit-IV (09 Hrs.):

5. Clinical safety testing: Irritation, sensitization, photo irritation, photoallergy, ocular irritation and protocols for the same.
6. Regulatory requirements: Manufacturing and sale of cosmetics.
7. Herbal cosmetics: Formulation development

Unit-V (09 Hrs.):

8. Packaging: Package development and design for cosmetics including aerosol packs.
9. Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

Recommended books:

1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2. J.B.Wilkinson and R.J. Moore; Harry's cosmetology; Longmr,J' Science and Technical.
3. S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E.G.Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M.S.Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder ; Cosmetic Ingredients, their safety assessment; Pathotox.
7. H.R.Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
9. C.G.Gebelein, T.c.Cheng and V.c. Yang; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W.A. Poucher; Poucher's Perfumes, cosmetics and soaps; yol. 3, Chapman and Hall
12. Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker

M.PHARM. III SEMESTER: SESSION (2013-14)

COURSE – ELECTIVE – II : IMMUNOLOGY AND IMMUNOASSAYS(THEORY)

Course Code : PHSE-3202

03hrs/week

Unit-I (09 Hrs.):

Basic Principles:

- Cells of the immune system.
- Non specific immunity.
- The specific immunologic response: Antigens and antigen-body binding Immunoglobulines.
- The humoral immune response
- The cellular immune response
- The control of immune response
- The complement system

Unit-II (09 Hrs.):

Pharmacological aspects of clinical conditions involving immunological mechanism:

- a) Hypersensitivity
- b) Delayed hypersensitivity
- c) Immunomodulators

Unit-III (09 Hrs.)

Current concepts in therapy and research of drugs for:

- a) Acquired Immuno Deficiency Syndrome (AIDS)
- b) Tissue transplantation (Immunosuppressants and immunoenhancers)
- c) Cancer
- d) Vaccines and sera
- e) Antifertility drugs and vaccin
- f) Drug allergy

Methods for (invitro and invivo) evaluation of influencing immune system drugs.

Biochemical tests used in immunology laboratory.

Unit-IV (09 Hrs.)

Radioimmassays (RIA): Enzyme multiplied Immuno assay techniques (EMIT)

Fluorescence polarization Immunoassay (FPIA)

Enzyme linked Immunosorbent Assay (ELISA)

Apoenzyme - Reactivation Immunoassay (NIA)

Substrate labeled fluorescence immunoassay (SLFIA)

Prosthetic group labeled Immunoassay (PGLI)

Immunomodulators of Indigenous origin (plants)

Fc Receptors:

Unit-V (09 Hrs.):

Introduction, structure and function of antibodies, confirmation of antibodies, Fc γ R family, Proteins, transcripts and genes: Gene, structure and actions of high affinity. Fc receptor for immunoglobulin E. binding factors. E .

Fc - receptor mediated killing.

Fc – receptor on T and B lymphocytes

Immunoglobulin binding factors

Recommended Books :

- 1) Kirkwood E and Catriona L. 'Understanding Medical Immunology (John Wiley and Sons New York)
- 2) Humphrey J.H. and White RG. Immunology for students of medicines (Blackwell Scientific Publication London)
- 3) Goodman and Gilman. The pharmacological Basis of therapeutics (9th Ed.) McGraw Hill, 1996)

M.PHARM. III SEMESTER: SESSION (2013-14)
COURSE – ELECTIVE - III: PHYTOPHARMACEUTICALS AND NUTRACEUTICALS
(THEORY)

Course Code : PHSE-3203

03hrs/week

Unit 1 (9 Hrs):

Phytomedicines – characteristics of Phytomedicines, synergy. Traditional systems of herbal medicines.

Unit-II (9 Hrs):

An overview of important natural products and Phytomedicines used for:

- i) Gastro intestinal and biliary disorders
- ii) Cardio vascular system
- iii) Respiratory system
- iv) Skin
- v) Supportive and protectives for stress, ageing, debility and cancer
- vi) Endocrines

Unit-III (9 Hrs):

Phytopharmaceuticals its therapeutic usage. Source, phyto-chemistry and physiological activities of Taxol, Camptothecin, podophyllotoxin, Genistein, Hypericin, Valproic acid, Ginkgolides, Colchicine, Streptokinase, Curcuminoids, guggulipids, boswellic acid.

Unit-IV (9 Hrs):

Nutraceutical approach for health management. Overview of internationally marketed nutraceuticals and functional Foods.

Unit-V (9 Hrs):

Issues of quality control of Phytomedicines and nutraceuticals , various approaches for quality control and standardization of raw materials, extracts and formulation

Recommended books:

1. Pharmacognosy and Phytotherapy: Heinrich, Barnes, Gibbon and Williamson – Churchill, Living Stone, London
2. Pharmacognosy – Trease and Evans
3. Pharmacognosy, Phytochemistry and Medicinal plants – Brunton
4. W.H.O. Monographs on herbal drugs
5. Herbal Medical Products, Dr. Fruké Gaedeke and Dr. Brbare Steinholf

M.PHARM. III SEMESTER: SESSION (2013-14)
COURSE – ELECTIVE -IV: ADVANCED PHARMACEUTICAL CHEMISTRY (THEORY)
Course Code : PHSE-3204 03hrs/week

Unit-I (09 Hrs.):

Stereochemistry and the chemistry of the side chain of cholesterol. Conformation of steroid nucleus. Chemistry of oestrone and corticosterone chemistry excluding the synthesis of conessine, strophanthidine, provitamin D. Structure action activity relationship of sex hormones.

Unit-II (09 Hrs.):

A study of phenothiazine tranquilizers and antidepressants, Structural requirements for the antithyroid activity, non-steroidal antiinflammatory drugs,

Unit-III (09 Hrs.):

antihyperlipedemic agents, polypeptides like oxytocin, insulin and hemoglobin (excluding of structure).

Elucidation of structure of ascorbic acid, vitamin A, vitamin K and tocopherols.

Unit-IV (09 Hrs.):

A study of structural analogues of morphine and the structural activity relationship study of morphine and reserpine

Unit-V (09 Hrs.):

Acetate hypothesis and its role in the biosynthesis. A study of aminoacids as the precursors for biosynthesis of some selected heterocyclic and nonheterocyclic alkaloids.

Books:

1. Organic chemistry YoUI by I.L. Finar, ELBS, New Delhi
2. Steroids by P.S.Kalsi, Kalyani Publisher
3. Principals of Medicinal Chemistry by W.O. Foye, T.L. Lemke, D.A. Williams, B.I. Waverly Pvt. Ltd. ,New Delhi.
4. Med. Chern. By Burger