Introduction

M. Pharm . course in Department of Pharm aceutical Sciences, Doctor Haris ingh Gour Vishwavidyalaya, Sagar of Madhya Pradesh was started in 1957.The M. Pharm. course will pave the way of the candidates for the higher studies in the field of pharmaceutical sciences. This course increase the knowledge and understand of the particular specialization. Candidate interested to opt for the teaching positions in various academic institutes needs to undertake this course. The department is one of the most prestigious institutes of pharmacy education and stands eleventh in the NIRF ranking for the session 2016-2017. At present the department has 50 M. Pharm. seats. It offers specialization in the following four branches.

Pharmaceutics: 20
Pharmaceutical Chemistry: 10
Pharmacognosy: 10
Pharmaceutical Biotechnology: 10

Students are getting scholarship from AICTE for this course. Students are placed in the government, private and semi government sector after doing their PG from this institute.

M. Pharm.

A - General

1. Name of the programme: M. Pharm.
2. Duration of Programme : The programme study for M. Pharm. shall extend over a period of four Semester.
3. Structure of programme : The course (elective and core) of study for B. Pharm. includes the subject, number of hrs. per week devoted to each subject and credits for its theory, practicals, tutorials as per scheme attached
4. Medium of instruction: English
5. Each courses of M. Pharm. is mark as a core/compulsory /Elective courses /open elective courses etc.
6. Credit allotted:
   i. Core course :89
   ii. Elective : 03
   Total: 92
9. Scheme of Examination:
   (a) Mid Semester Examination :20 Marks
   (b) Internal Assessment :20 Marks
   (c) End Semester Examination :60 Marks

B - Assessment

1) Internal Assessment:

a) Each theory course contains methodology of assessment i.e. assignment, presentation, group discussion etc. depending on the number of students in the class and feasibility of adopting a particular methodology. The distribution of marks for Internal Assessment is as follows:

(i) Evaluation of the assignment, Presentation, group discussion etc. :15 Marks.
(ii) Attendance :05 Marks

The marks for attendance is awarded as follows:

(i) 75% and below :00 Mark
(ii) >75% and upto80% :01 Mark
(iii) >80% and upto85% :02 Mark
(iv) >85% and upto90% :03 Mark
(v) >90% and upto95% :04 Mark
(vi) Above 95% :05 Mark

b) Practical/Lab Courses:

1. Evaluation of Practical/Lab Courses is as follows:

(i) Performing and getting the experiment checked regularly and Incorporating the suggestion in the practical note book : 15 marks

(ii) Attendance : 05 marks

The marks for attendance is awarded as follows:

(i)	75% and below	:00 Mark
(ii)	>75% and upto80%	:01 Mark
(iii)	>80% and upto85%	:02 Mark
(iv)	>85% and upto90%	:03 Mark
(v)	>90% and upto95%	:04 Mark
(vi)	>95%	:05 Mark

A student must have attendance of 75% for appearing in any examination.

A student must appear in Mid Semester Examin ation and Internal Assessment to be eligible to appear End Semester Examination.

C) End Semester Examination for Practical/Lab Courses:

It consist of 60marks as follows:

(a) Assessment of performance in the experiment :50 Marks

(b) Viva – Voce of Experiment :10 Marks

D) Evaluation of Projects:

It is based on periodic assessment of the progress of the project End Semester Examination as follows:

(i) First periodic assessment of the progress after 08 weeks :30 Marks

(ii) Second periodic assessment after 04 weeks :10 Marks

(iii)End semester Examination consist of

(a) Evaluation of Projects report on the field work :40 Marks

(b) Viva Voce of the project rep ort :20 Marks

E) Evaluation of Seminars:

1. Documentation for the seminar :20 Marks
2. First presentation of the seminar :20 Marks
3. End Semester Examination :60 Marks

End Semester Examination consists of

(I) Presentation of the seminar :40 Marks

(II) Defense of the presentation :20 Marks

Question paper pattern for End semester examination

Total marks: 60

1. Multiple choice questions: 10 questions x 1 = 10
2. Short answers 6 (attempt any four questions) x 5 = 20
3. Long answers 5 (attempt any three questions) x 10 = 30

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	PHS CC 1201	Methods in Pharmaceutical Research (MPR)	**4**	**-**	**-**	**4**
		Course II	PHS CC 12 02	Product Development	**4**	**-**	**-**	**4**
		Course III	PHS CC 12 03	Pharmaceutical Biotechnology	**4**	**-**	**-**	**4**
		Course IV	PHS CC 12 04	MPR Practicals (P)	**-**	**-**	**8**	**4**
		Course V	PHS CC 1205	Product Development Practicals (P)	**-**	**-**	**8**	**4**
		Course VI	PHS CC 1206	Pharmaceutical Biotechnology Practicals (P)	**-**	**-**	**8**	**4**
				Total Credits	**12**	**-**	**24**	**24**

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	PHS P CC 22 01	Advanced Pharmaceutics	4	-	-	4
		Course II	PHS P CC 22 02	Biopharmaceutics and Pharmacokinetics	4	-	-	4
		Course III	PHS P CC 22 03	Controlled and Novel Drug Delivery System (NDDS)	4	-	-	4
		Course IV	PHS P CC 22 04	Advanced Pharmaceutics	-	-	16	8
		Course V	PHS P CC 22 05	DRA; IPR and QA	4			4
		Dissertation Project PHSP CC 22 06		Dissertation Project				4
				Total Credits	16		16	28

M. Pharm. Course: SECOND SEMESTER : Specialization: Pharmaceutical C hemistry

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	PHS C CC 22 0 1	Drug Design and Discovery	**4**	**-**	**-**	**4**
		Course II	PHSC CC 22 0 2	Advances in Medicinal Chemistry	**4**	**-**	**-**	**4**
		Course III	PHSC CC 22 0 3	Advanced in Organic Chemistry	**4**	**-**	**-**	**4**
		Course IV	PHSC CC 22 0 4	Advanced Pharmaceutical Chemistry Practical (P)	**-**	**-**	**16**	**8**
		Course V	PHSC CC 22 0 5	DRA;IPR and QA	**4**			**4**
		Dissertation Project PHSC CC 22 0 6		Dissertation Project				**4**
				Total Credits	**16**		**16**	**28**

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	PHSG CC 22 0 1	Natural Products	**4**	**-**	**-**	**4**
		Course II	PHSG CC 22 0 2	Advanced Pharmacognosy	**4**	**-**	**-**	**4**
		Course III	PHSG CC 22 0 3	Plant Biotechnology	**4**	**-**	**-**	**4**
		Course IV	PHSG CC 22 0 4	Advanced Pharmacognosy (P)	**-**	**-**	**16**	**8**
		Course V	PHSG CC 22 0 5	DRA;IPR and QA	**4**			**4**
		Dissertation Project PHS G CC 22 0 6		Dissertation Project				**4**
				Total Credits	**16**		**16**	**28**

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	PHSB CC 22 0 1	Advanced Biotechnology	4	-	-	4
		Course II	PHSB CC 22 0 2	Molecular Biology And Genetic Engineering	4	-	-	4
		Course III	PHSB CC 22 0 3	Industrial Biotechnology	4	-	-	4
		Course IV	PHSB CC 22 0 4	Pharmaceutical Biotechnology (P)	-	-	16	8
		Course V	PHSB CC 22 0 5	DRA/IPR/QA	4			4
		Dissertation Project PHS B CC 22 0 6		Dissertation Project*				4
				Total Credits	16		16	28

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:
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	PHS EC 3201 PHS EC 3202 PHS EC 3203 PHS EC 3204	Elective* I,II,III,IV	3	-	-	3
		Project Major	PHSP CC 3205 PHSC CC 3205 PHSG CC 3205 PHSB CC 3205	Project Major	-	-	-	12
		Project Minor	PHSP CC 3206 PHSC CC 3206 PHSG CC 3206 PHSB CC 3206	Project Minor	-	-	-	05
				Total Credits	3		-	20

*** Elective Papers & Course Code:**

i) Cosmeticology : PHS E C 32 0 1
ii) Immunology and Immunoassays : PHS EC 32 0 2
iii) Phytopharmaceuticals and N utraceuticals : PHS EC 32 0 3
iv) Advanced Pharm. Chemistry : PHS EC 32 0 4

M. Pharm. Course: FOURTH SEMESTER:
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)		PHSP CC 4201 PHSC CC 4201 PHSG CC 4201 PHSB CC 4201	Project Major	-	-	-	20
				Total Credits	-		-	20

* Major Project Valuation by Ex ternal Examiner

M.PHARM. -I SEMESTER: COMPULSORY
COURSE -I METHODS IN PHARMAC EUTICAL RESEARCH

Course Code : PHS CC -1201 **04hrs/week**

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC -MS, GC -MS, UPLC, OPLC and chiral chromatography

Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- develop theoretical and practical skills of the hyphenated instruments
- qualitative and quantitative estimation of compounds
- identifica tion of unknown organic compounds

LOCF :

Upon successful completion of the course, the student will be able to:

01	Describe the NMR spectroscopy and interpretation of PMR spectra of common organic compounds. They will also know about the ^{13}C -NMR and 2 D NMR.
02	Explain the Mass Spectroscopy, IR spectroscopy and will be able to interpretate Mass spectra and IR spectra.
03	Explain the HPLC technique and its instrumentation and adsorption, partition, reverse phase, chemically bonded phase, ion exchange, Io nic -pair, affinity, size exclusion and chiral chromatographic methods.
04	Explain the LC/MS, GC/MS, UPLC, OPLC and chiral chromatography and various thermal methods (TGA, DTA and DSC) for the analysis of pharmaceutical formulations and raw materials.
05	Describe the SEM, TEM and STEM, Scanning probe microscopy, Electron diffraction, X -Ray diffraction, electrophoresis and other advanced techniques for analysis at molecular levels.

Unit -I (12 Hrs.):

Basic theoretical background of NMR spectroscopy, interp retation 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, Ion ic- ion -pair, affinity, size exclusion and chiral chromatographic methods.

Unit -IV (12 Hrs.):

Advanced Chromatographic techniques: LC/MS, GC/MS, UPLC, OPLC and chiral chromatography
Introduction of various thermal methods (TGA, DTA and DSC) - theories, i nstrumentation and applications.

Unit -V (12 Hrs.):

Electron microscopy General principles of SEM, TEM and STEM, Scanning probe microscopy.
Electron diffraction, X -Ray diffraction theory instrumentation and applications
Electrophoresis: theory instrumentat ion and applications of Capillary and Gel Electrophoresis. SDS -PAGE and other advanced 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. Phar maceutical 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

COURSE – II: PRODUCT DEVELOPMENT

Course Code : PHS CC -1202 **04hrs/week**

Scope

This subject deals with various pharmaceutical formulations including solid dosage form, liquid dosage form, topical and sustained release formulations, their scale up technique and packaging requirement

Objectives

Upon completion of this course the student should be able to know

- Manufacturing and evaluation techniques of various pharmaceutical formulations
- Various packaging materials for these formulation
- Stability assessment of these formulation
- Sustained release dosag e forms

LOCF :

Upon successful completion of the course, the student will be able to:

01	Describe the formulation considerations and *in vitro - in vivo* evaluation techniques; cGMP, stability kinetics and stability in pharmaceuticals. Explain the experiment by design, optimization techniques, and application of DoE in QbD with application to pharmaceutical product development.
02	Design and evaluate tablets, oral liquids, parenterals, ophthalmics, and depot products.
03	Explain the topical and rectal formulations & evaluation and sustained release dosage forms concept.
04	Explain the Pilot -plant and scale -up techniques. Describe the pharmaceutical packaging and stability assessment.
05	Describe the classification of data and use of various statistical methods and sampling plans .

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. Stability in Pharmaceuticals and Study of stability kinetics

Experiment by Design: Overview and scope of Experimental design, Screening, factor influence studies, selection of design for optimization, Optimization techniqu es in Pharmaceutical Formulations and processing: Plackett burmann design, Full Factorial and fractorial factorial design, D -optimal, Response surface methodology, Application of DoE in QbD with application to pharmaceutical product development, important computer software's for DoE

Unit -II (12 Hrs):

Designing of Pharmaceuticals -
Tablet formulation, Special tablets, preparation of components for compression, characterization of granulation, Coating of tablets, Evaluation of tablets, Equipments and pr ocessing problems in tablet.
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):

Topical and rectal Absorption of drugs, formulations and evaluation.

Sustain Release dosage forms: Concept, Theory: design, Zero order release approximatio n, first order release, multiple dosing, implementation of designs, evaluation and testing.

Unit -IV(12 Hrs):

Pilot -plant and scale -up techniques
Packaging of Pharmaceuticals -
Types of containers and closures, packaging and stability assessment.

Unit -V (12 Hrs):

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

Books Recommended: -

1. Lachmann, L., Lieberman, H.A. & Kanig, J.I.: The Theory and Practice of Ind ustrial 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. & Carle ss, 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
9. Vyas S.P. and R. K. Khar Controlled Drug Delivery, Vallabh Prakashan

M.PHARM - I SEMESTER : COMPULSORY

COURSE -III: PHARMACEUTICAL BIOTECHNOLOGY

Course Code : PHS CC -1203 **04hrs/week**

Scope

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to know about enzyme immobilization, genetics and genetics disorders, recombinant DNA technology and also to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective

At the complet ion of this subject it is expected that students will be able to

- Perform enzyme isolation using advanced techniques
- Understand the new techniques in biotechnology and tools and their uses in drug and vaccine development.
- Identify appropriate sources of enz ymes.
- Understand and perform genetic engineering techniques in gene manipulation, r -DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologi cs, devices, and drug - device combinations

LOCF :

Upon successful completion of the course, the student will be able to:

01	Describe the enzyme, and p erform enzyme isolation using advanced techniques. Identify appropriate sources of enzymes.
02	Explain various types of enzymes immobilization techniques and basis of genetics.
03	Describe genetic engineering techniques in gene manipulation, r -DNA technology, pharmacogenomics and gene amplification. Explain immune system.
04	Describe the antigen capture and presentation , major histocompatibility complex and its classification , presentation of antigen proteins , autoimmunity and hypersensitive response. Explain the B cell, T Cell maturation process, vaccines, hybridoma technology .
05	Describe the enzyme, a nd enzyme isolation using advanced techniques.

Unit -I (1 2 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 materiel, 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 amplication 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, anto-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 -II (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. Advances in Pharmaceutical Biotechnology Vyas S.P. & Kumar H.D., CBS Publishers New Delhi
3. Gene VII: Lewin Benzamin.
4. Industrial Microbiology: L.E. Casida.
5. Biotechnology - The Biological Principles: M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury.
6. Microbial Genetics: David Freifelder.
7. Immunology: J. Kuby.
8. Immunology: Weir.

M.PHARM. I SEMESTER

COURSE -IV: METHODS IN PHARMACEUTICAL RESEARCH (P)

Course Code : PHS CC -1204 **08hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01	Perform experiments based on structure, chemical environment of molecules, number of the signals present in the molecule which can assign structures to simple molecules on the basis of nuclear magnetic resonance spectra .
02	Perform experiments based on separation of molecular ions on the basis of their mass and charge.
03	Perform experiments based on determin ation of the structure of a compound by observing its fragmentation and determine the chemical functional groups in the sample.
04	Perform experiments based on separation of volatile organic compounds, mass, temperature or *heat* flux. level of inorganic and organic components in materials.
05	Perform experiments based on three -dimensional and topographical imaging, information on element and compound structure and crystallographic structure of a material, separation of DNA, RNA or protein molecules

Practical's :

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

COURSE -V : PRODUCT DEVELOPMENT (P)

Course Code : PHS CC -1205 **08hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01	Perform experiments based on formulation development of compressed tablets, topical preparations, oral liquids.
02	Perform experiments based on formulation development of stable suspensions and dry suspensions, emulsions, small volume parenterals.
03	Perform experiments based on formulation development of ophthalmic preparations .
04	Perform experiments based on assessment of stability studies according to ICH guidelines.
05	Perform experiments based on evaluation of packaging material s and product development of sustained release dosage forms

Experiments based on following concepts:

- Formulation development of compressed tablets.
- Formulation development of topical preparations.
- Formulation development of oral liquids.
- Formulation development of stable suspensions and dry suspensions.
- Formulation development of emulsions.
- Formulation development of small volume parenterals.
- Formulation developm ent of ophthalmic preparations.
- Assessment of stability studies according to ICH guidelines.
- Evaluation of packaging materials.
- Product development of sustained release dosage forms.

Books recommended:

1. Conners KA., A text book of Pharmaceutical Analysis ,W ells J.U., Pharmaceutical Preformulation": The Physico -chemical properties of drug substances, Ellis Horwood Lod. England 1998
2. Lachmann, L., Lieberman, H.A. & Kanig, J.I.: The Theory and Practice of Industrial pharmacy. Lea and Fibiger, Philadelphia.
3. Banker, G.S. & Rhodes, C.T. : Modern Pharmaceutics, Marcel Dekker Inc. New York and Basel.
4. Turco, S. & King R.E. : Sterile Dosage Forms, Lea and Febiger, Philadelphia
5. Bean, H.S., Backett, A.H. & Carless, J.E: Advances in Pharmaceutical Sciences, Aca demic Press, London and Newyork.
6. Jain, N.K.: Controlled and Novel Drug Delivery , CBS, Delhi
7. Robinson, J.R. & Lee, V.H.L.: Controlled Drug Delivery, Marcel Dekker, New York and Basel.
8. Chien,Y.W.: Novel Drug Delivery Systems, Marcel Dekker,New York and Base l
9. Jain N. K. Pharmaceutical Product Development, CBS Publisher, Delhi
10. Vyas S.P. and R. K. Khar Controlled Drug Delivery, Vallabh Prakashan
11. Jain Sanjay K, Soni Vandana and Rawlin E. A., Bentley's Text Book of Pharmaceutics, Elsevier India Private Ltd, 2012

M.PHARM. I SEMESTER

COURSE -VI: PHARMACEUTICAL BIOTECHNOLOGY (P)

Course Code : PHS CC -1206 **08hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01	Perform experiments based on protein estimation by UV spectrophotometer, Lowry and Bradford method .
02	Perform experiments based on isolat ion of DNA from cheek cells, onion and determination of concentration and purity of protein in a sample .
03	Perform experiments based on effect of various factors on enzyme activity
04	Perform experiments based on blotting techniques .
05	Perform experiments based on extraction of enzyme and immobilization of enzyme(s).

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 F reifelder.
6. Immunology: J. Kuby.
7. Immunology: Weir.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP

COURSE - I: ADVANCED PHARMACEUTICS

Course Code : PHS P CC -2201 **04hrs/week**

Scope

This course is designed to impart knowledge and skills necessary to train the students with the recent advances in tablet, parenteral and microencapsulation technology.

Objectives

At completion of this course it is expected that students will be able to u nderstand,

- Recent advances in tablets and microencapsulation technology
- Stability indicating assay
- Radiopharmaceuticals

LOCF :

Upon successful completion of the course, the student will be able to:

01 Describe the recent advances in tablet, parenteral , microencapsulation technology , process automation pharmaceutical manufacturing , GMP, QA and validation.

02 Explain the formulation concepts of the vitamins & antibiotics products , disperse system and methods of solubility enhancement.

03 Describe the coarse dispersion systems, micro & multiple emulsions , rheology, drug kinetics and drug diffusion in coarse dispersion systems.

04 Explain the stability indicating assays, advances in pharmaceutical packaging and polymer sciences and its applications.

05 Describe the production, control & applications of the radiopharmaceuticals and various kinds of medical devices & implants.

Unit -I (12 Hrs.):

Recent advances in Tablet Parenteral and Microencapsulation technology.
Process automation in pharmaceutical manufacturing, role of GMP, Quality assurance and validation.

Unit -II (12 Hrs.):

Formulation development of vitamin s and antibiotics products.
Disperse systems - Molecular dispersion, solubilization theory, Methods of solubility enha ncement, 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, rheol ogy 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 applicatio ns in pharmacy.

Unit -V (12 Hrs.):

Radiopharmaceuticals - production, control and its applications.
Medical devices/ implants: Functional requirements, effects of the device on the body, effect of the body on the device, benefit/risk ratio, scaffolds for cartilage repair, implants for bone, implants for plastic surgery , cardiovascular prostheses and stents , devices for nerve regeneration, musculoskeletal, soft tissues. Dental and otologic implants.

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: Parenternal Medication Vol. I and II.
3. Turco, S. and King, R.F., Sterile Dosages Forms., Lea and Febiger, Philadelphia.
4. Reming ton's Pharmaceutical Siences.
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.
7. Regulatory requirement of medical devices
8. Various case studies……..
9. Biodesign: The process of innovating medical technologies. Zenios, Makower, Yock Co Press.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP

COURSE - II: BIOPHARMACEUTICS AND PHARMACOKINETICS

Course Code : PHS P CC -2202 **04hrs/week**

Scope

This course deals to impart knowledge regarding pharmacokinetics and pharmacodynamics of drugs and to apply them for practical consideration

Objectives

Upon completion of this course it is expected that students will be able to understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and eliminati on.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

LOCF :

Upon successful completion of the course, the student will be able to:

01	Explain the transport of drug through biological members other than GIT and drug dissolution mechanism
02	Deign for the assessment of bioavailability and bioequivalence as well as *In vitro - In vivo* correlations
03	Demonstrate the kinetics of compartment modeling on IV and oral administration of single and multiple dosing.
04	Explain the Clinical kinetics with reference to ADME. And therapeutic regimen.
05	Describe the MRT and Michaelis - Menton kinetics.

The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Unit -I (12 Hrs.):

Transport of drugs through membrances 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.

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

Unit -II (12 Hrs.):

Bioava ilability 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 multip le 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 intervenous administration, and first order absorption of single dosing. Pharmacokinetics of sustained release dosages forms.

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 resp onse 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 limitatio n 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 wi th Michaelis - Menton kinetics, determination of Km and Vm, non -linear tissue binding constants.

Books recommended :-

1. Gibaldi M., Pharmacokinetics, Marcel Dekker Inc. New York.
2. Abdou, H.M. Dissolution, Bioavailbility 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 Bioequivalance, Marcel Dekker Inc., New York
6. Gibalidi,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,ABC.:Applied Biopharmaceutics & Pharmacokinetics,Appleton and lange, Connecticut, USA.
9. Hotari, R.E., Biopharamaceutics and clinical pharmcokinetics, Marcel Dekker Inc., New York and Basel.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP

COURSE - III: CONTROLLED AND NOVEL DRUG DELIVERY SYSTEMS

Course Code : PHS P CC-2203 **04hrs/week**

Scope

This course deals with imparting knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective

On completion of this course students will be able to understand,

- Design, development of sustained and controlled release dosage form
- Need to develop sustained and controlled release dosage form
- Manufacturing and evaluation of various novel drug deliver y systems

LOCF :

Upon successful completion of the course, the student will be able to:

01	Explain the working of various equipment used in the advanced pharmaceutics experiments
02	Describe the advances in the formulation development of the pharmaceutical products.
03	Describe the compartment modelling, non -compartment modelling,
04	Describe the role of biopharmaceutics and various pharmacokinetics parameters on the pharmaceutical products.
05	Describe the formulation and evaluation of various types of novel, sustained and controlled drug delivery systems.

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.
Parenetral products.
Implantable products.

Unit -III (12 Hrs.):

Transdermal therapeutic system.
Prodrugs as sustained chemical delivery systems.
Biochemical and Molicular 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.
5. Roseman, T.J.: Controlled Release Drug Delivery Ssytems, Marcel Dekker New York
6. Goldberg : Targeted Drugs.
7. Bruck, S.D., Control led Drug Delivery , Vol. I & II.
8. Juliano, R.L. : Drug Delivery Systems.
9. Review articles published in various journals.
10. Jain, N.K.: Progress in Controlled and Novel Drug Delivery, CBS Publisher, New Delhi.
10. Vyas S.P. & Khar R.K.: Targeted & Controlle d Drug Delivery ,CBS Publisher, New Delhi.
11. Vyas S.P. : Theory & Practice in Novel Drug Delivery Systems, CBS Publisher, New Delhi.

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP

COURSE - IV: ADVANCED PHARMACEUTICS (P)

Course Code :PHS P CC -2204 **16hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01	Perform the experiments based on various analytical equipment (s) used in advanced pharmaceutics experiments.
02	Perform the experiments based on the advances in the formulation development of the pharmaceutical products.
03	Describe the compartment modelling, non -compartment modelling, role of the biopharmaceutics .
04	Perform the experiments based on role of various pharmacokinetics parameters on the pharmaceutical products .
05	Perform the experiments based on the formulation and evaluation of various types of novel, sustained and controlled drug delivery systems.

(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 Pharm acokinetics

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 Deliv ery 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. Prep aration and characterization of osmotic pumps.

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: Parenternal Medication Vol. I and I I.
3. Gibaldi M., Pharmacokinetics, Marcel Dekker Inc. New York.
4. Abdou, H.M. Dissolution, Bioavailbility and Bioequivalence, Mack Publishing Co. Easton , PA
5. Smith, R.V. & Stewart, J.T., Text book of Biopharmaceutical Analysis, Lea and Febiger, Philadelphia.
6. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York and Basel.
7. Jain, N.K.: Controlled and Novel Drug Delivery,CBS, New Delhi.
8. Vyas S.P. & Khar R.K.: Targeted & Controlled Drug Delivery,CBS Publisher, Ne w Delhi.
9. Jain Sanjay K, Soni Vandana and Rawlin E. A., Bentley's Text Book of Pharmaceutics, Elsevier India Private Ltd, 2012

M.PHARM. II SEMESTER: PHARMACEUTICS GROUP

(COMPULSORY PAPER FOR ALL SPECIALIZATIONS)

COURSE - V: DRA, INTELLECTUAL PROPER TY RIGHTS AND QUALITY ASSURANCE

Course Code : PHS P CC-2205 **4hrs/week**

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

Objectives :

Upon completion of the course, it is expected that the students will be able to understand

- Regulatory guidelines (WHO, GMP, GLP etc) for pharmaceuticals
- Validation protocol for pharmaceutical formulation
- Sampling design and methods
- In-process quality control parameters

LOCF :

Upon successful completion of the course, the student will be able to:

01 Describe the Drugs and Cosmetics Acts and rules, Drug Regulatory Affairs; GMP, cGMP, GLP requirements as per the USFDA, WHO Guidelines and ISO 9000 series; Documentation and Maintenance of records in the pharmaceutical industry.

02 Describe the preparation of documents for NDA and Export Registration; Intellectual Property Rights. Also learn the disposal of sewage and pollution control in pharmaceutical industry.

03 Explain the concepts in Validation and its application; concepts of QC&QA, Source and Control of Quality Variation of raw materials, containers, closures, personnel, environment .

04 Describe the In -process quality tests, In -process quality control problems in pharmaceutical industries and international council for harmonization (ICH) guidelines.

05 Describe the sampling plans, sampling and characteristic curves. Also understand the master formula generation & maintenance, and Standard Operating Procedures (SOP) for different dosage forms.

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 Expo rt 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, IPQ C 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 Phaarmaceutics" 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

COURSE - I: DRUG DESIGN AND DISCOVERY

Course Code: PHS C CC -2201 **4hrs/week**

Scope

The subject is designed to impart knowledge regarding various computational techniques involved in drug design and discovery.

Objectives

At completion of this course it is expected that students will be able to understand

- Significance of CADD in drug discovery
- Computational techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- In-silico virtual screening protocols

LOCF :

Upon successful completion of the course, the student will be able to:

01 Describe the historic initiation of drug design and discovery study & its relevant connection with cell biology and genomics; the parameters like thermodynamic considerations, physical basis of intermolecular interactions, total energy intermolecular interaction.

02 Describe the concept of stereo -specificity; significance of stereochemistry, bioisosterism, 3D structure derivation in software aided drug design & its optimization.

03 Explain the theory of Pharmacophore elements and representation, 3D Pharmacophore models & its implementation to describe pharmacophoric approach in Computer aided drug design; Hypothesis of 3D QSAR, impo rtance of Hansch and related approaches& different statistical method linked with QSAR to deduce several biological and physiochemical data of a scaffold or ligand -receptor interaction.

04 Describe the different novel approaches and methods like Nucleic a cid -based drug design, prodrug &retrometabolism approach in drug design and discovery.

05 Explain the theory of High throughput screening, combinatorial chemistry & concept of deconvolution techniques in lead discovery

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 a nd thumb rules.

Unit -II (12 Hrs.):

]3. Stereochemistry and drug design: Sterospecificity 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. C omputer 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, salva tion effects, examples of 3D Pharmacophore models and their uses.

7. QSAR: Fundamentals of QSAR, biological data, contribution of groups in additivity , Hansch analysis and related approaches, physicochemical properties, statistical methods in QSAR, applica tion 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 m ethods, conformational analysis, Pharmacophore identification, molecular modeling in 3D QS AR -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 de sign : Aim, types, groups involved, methods, metabolite considerations and application , Bioprecursers

11. Retrometabolism approach to drug design and targeting.

Unit -V (12 Hrs.):

12. High throughput screening for lead discovery

13.Combinatorial chemistr y including solid state.parallel & liquid phase, synthesis , identification of hits & concept of deconvolution.

Books r ecommended:

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

COURSE - II: ADVANCES IN MEDICINAL CHEMISTRY

Course Code : PHSC CC -2202 **4hrs/week**

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Receptor drug interaction
- Different medicinal agents and their mechanism of action
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biol ogical targets

The following topics shall be dealt with recent advances :

LOCF :

Upon successful completion of the course, the student will be able to:

01 Explain structure and the chemistry of cell membranes, different drug and various receptors and their interaction with drugs, accordingly, they learn how the chemical structure of the drug dramatically increases or decreases the affinity for different types of the receptors

02 Describe the modern hypothesis that modulate the specific enzyme therapeutic value along with various interactions such as non -covalent and covalent bonds with the different enzymes and enzyme inhibitors.

03 Describe the neuro -modulatory role of NO in the various body system. In addition, they will learn the e ffect of modulation or inhibition of the NO in the diseased condition and recent developments of endorphins and new antidiabetic drugs .

04 Describe the SAR, mechanism of action and chemical structure that acts on the Cardiovascular system along with the nomenclature, SAR and metabolism of prostaglandin and eicosanoids

05 Describe the mechanism by which cancer is taking place, different oncogenes responsible for Cancer generation and the mechanism of an intercalating agent that acts as an antineoplastic agent. They will also understand the Drug Discovery of different Anti -viral drugs and Retrovirus pathogenesis

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).

Unit – II (12 Hrs.):

Rational design of enzyme inhibitors.

a. Design of non – covalently binding enzyme 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, revers e transcriptase, catechol -o- methyl transferase, ACE, glycinamide ribonucleotide transformylase, HMG Co A reductase inhibitors, antimetabolites, dihydrofolate reductase inhibitors ,PDE, protein kinase.
c. Design of covalently binding enzyme inhibitors, compet itive 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 inhibi tors.

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 isoenzy mes , nitric oxide synthetase inhibitors, cytotoxic role of nitric oxide , therapeutic significance of NOS inhibitors & nitric oxide.

Endorphins: discovery of enkephalins and endorphins resent development.

Antidiabetics

Unit – IV (12 Hrs.):

Advances in medicinal chemistry of cardiovascular, anti -arrhythimics, anti -anginal, anti -hypertensive ,anti -hyperlipidemics and chemical contraceptives

prostaglandin & other eicosanoids: nomenclature, SAR, metabolism.

Unit – V (12 Hrs.):

Antineoplastics agents: moleculer 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 r ecommended:

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 appearin g 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

COURSE - III: ADVANCES IN ORGANIC CHEMISTRY

Course Code : PHSC CC -2203 **4hrs/week**

Scope

The subject is designed to provide knowledge about different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

- The concept of stereochemistry
- The various reaction intermediates
- The various catalysts used in organic reactions
- The concept of aromaticity

LOCF :

Upon successful completion of the course, the student will be able to:

01 Explain aromaticity, EDA complexes, crown ethers and inclusion compounds.

02 Describe about the Stereochemistry, optic al isomerism, chiral atoms, cis -trans isomerism fused ring systems and importance of chiral drugs.

03 Explain alkylation of enolates, oxygen versus carbon as the site of alkylation, alkylation of aldehydes, ester, amides& nitrile.

04 Describe the reactiv e intermediates, Free radicals and rearrangement reactions involving rearrangement to electron deficient carbon and nitrogen, oxygeninter and intra molecular aromatic rearrangements, mixed type of aromatic rearrangement.

05 Describe the elimination reacti ons - E2,E1& E1cbmechanisms. Also explain protection & deprotection of various groups, green chemistry, click chemistry and combinatorial chemistry.

Unit – I (12 Hrs.):

Concept of aromaticity involving ring systems, hydrogen bonding & other weaker bondings, EDA complexs, 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 qua drivalent chiral atoms, compound with tervalent 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, mono cyclic compounds,fused ring systems 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 mechanism s, 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 redicals: stability and reactivity of th ese intermediates.

Rearrangements:

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

Unit – V (12 Hrs.):

Synthetic strategies:

Protection & deprotection of various groups, disconnection approach, Syntho ns for carbon - carbon bond formation, b ifunctional compounds, selective functional group interconvertion (FGI).

Green chemistry: Basic principles, mic rowave and ultra sound as a source of energy, ionic liquids as reaction media: liquid phase and solid phase synthesis.

Combinatorial chemistry, d econvulation techniques and introduction to click chemistry.

Books Recommended:

1. J. March, Advanced organic che mistry, 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 e dition, Reaction& Sythesis, 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

COURSE - IV: ADVANCED PHARMACEUTICAL CHEMISTRY (P)

Course Code : PHSC CC -220 4 **16hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01 Explain structure aided drug design process, software's aided drug design, optimization of identified compounds.

02 Explain identification of pharmacophore, generation of 3D coordinates, geometry optimization and molecular modeling in 3D QSAR -CoMFA .

03 Explain computer aided drug design, Pharmacophore based ligand design, Pharmacophore concept, 3D Pharmacophore models.

04 Discuss reverse transcriptase, catechol -o-methyl transferase ACE, glycinamide ribonucleotide transformylase, HMG Co A reductase inhibitors, antimetabolites, dihydrofolate reductase inhibitors, PDE, protein kinase.

05 Describe the green chemistry, microwave and ultra sound as a source of energy, ionic liquids as reaction media, liquid phase and solid phase synthesis .

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.

Books Recommended:

1. Burger, A., Med. Chem.
2. Wilson and Gisvold, Organic Med. Pharmaceutical Chem.
3. Foye, Principals of Med. Chem.
4. T.J. Perun and C.L. Propst, Computer Aided Drug Design.
5. Monographs& relevant review articles appearing in various periodicals & journals.
6. Vogel, A. I. Textbook of practical organic chemistry including qualitative org anic analysis.
7. Indian Pharmacopoeia,. "7th Edn: ministry of health and Family welfare, Indian pharmacopeia commission, Ghaziabad." (2014).

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP
COURSE - I: NATURAL PRODUCTS

Course Code : PHSG CC -2201 **04hrs/week**

Scope

This course is deals with herbal products, regulatory guidelines for herbals, monographs, performance evaluation of cosmetic products used in cosmetic industries.

Objectives

At completion of this course student shall be able to understand

- Various herbal remedies
- Analysis of natural products and monographs
- Determination of Herbal drug -drug interaction
- Principles of performance evaluation of cosmetic products

LOCF:

Upon successful completion of the course, the student will be able to:

01 Explain methods used for studies of biosynthetic pathways of secondary metabolites and biosynthesis of phytoconstituents mentioned in syllabus.

02 Describe the extraction and isolation procedures used for botanical drugs mentioned in syllabus.

03 Explain Protocols and screening methods for anti -diabetic, anti -inflammatory, antihepatotoxic, antifertility and diuretic activities.

04 Describe the current status of plants used as anticancer and other therapeutic applications as mentioned in syllabus.

05 Explain the Herbs used as Health foods, Herbal cosmetics and Aromatherapy.

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, piperidine, tropane, quinoline, isoquinoline, indole and phenanthrone 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 artermesia. 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.

Books Recommended:

1. Pharmacognosy and Phytotherapy: Heinrich, Barnes, Gibbon and Williamson, Publishers: Churchill, Living Stone, London
2. Pharmacognosy – Trease and Eavan, Publisher Elsevier
3. Pha rmacognosy, Phytochemistry and Medicinal Plants - Jean Bruneton, Publisher, Intercept
4. W.H.O. monographs on herbal drug
5. Herbal Medicinal Products – Fruke Geadeke and Brbare Steinholf
6. Phytochemical Methods – Harbone
7. Indian Herbal Pharmacopeia
8. Plant Drug Ana lysis: A Thin Layer Chromatography – Wagner H and Baldts
9. Atlas of Microscopy of medicinal Plants – Culinary Herba and Spices, CBS Publisher
10. Thin layer Chromatography – Stahl
11. Phytochemistry and Plant Taxonomy – Bilgrami, CBS Publisher
12. Pharmacognosy – Gokh ale, Kokate and Purohit, Nirali Prakashan

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP
COURSE - II: ADVANCED PHARMACOGNOSY

Course Code : PHSG CC -2202 **04hrs/week**

SCOPE

To learn and understand the various microscopical techniques and photochemical method for drug evaluation

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Microscopic techniques
- Fluorescent techniques
- Taxonomy and chemotaxonomy
- Chemical constituents of plants as alkaloids, g lycosides, terpenoids, flavanoids etc

LOCF:

Upon successful completion of the course, the student will be able to:

01	Explain the quantitative microscopy and its application in herbal drug evaluation.
02	Describe the microchemical tests as applied to crude drugs and their constituents.
03	Explain analytical procedures and screening of vegetable materials for phenolic and other compounds of medicinal importance as mentioned in syllabus.
04	Describe the current status of botanical products used as therapeutic agents as mentioned in syllabus.
05	Explain the potentials of plants in cosmetic industry and nutraceuticals.

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, Flourescence analysis in evaluation of drugs.

Unit-III (12 Hrs):

Phytochemical Methods: -

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

Unit -IV (12 Hrs):

A study of history and development of taxanomy and chemotaxanomy. Artificial and natural systems of classification . Principles of classification .Rules of plant nomenclature and modern trends in taxanomy. Study of important families of medicinal a nd phylogenetic importence.

Unit -V (12 Hrs):

Chemica l constituents as taxonomic character s and their application in compa rative phytochemistry in special reference to alkaloids, glycosides, terpenoids, flavanoids and other pigments, lipids, acetylini c and sulphur compounds.

Books Recommended:

1. Pharmacognosy and Phytotherapy: Heinrich, Barnes, Gibbon and Williamson, Publishers: Churchill, Living Stone, London
2. Pharmacognosy – Trease and Eavan, Publisher Elsevier
3. Pharmacognosy, Phytochemistry and Medicinal Plants - Jean Bruneton, Publisher, Intercept
4. W.H.O. monographs on herbal drug
5. Herbal Medicinal Products – Fruke Geadeke and Brbare Steinholf
6. Phytochemical Methods – Harbone
7. Indian Herbal Pharmacopeia
8. Plant Drug Analysis: A Thin Layer Chroma tography – Wagner H and Baldts
9. Atlas of Microscopy of medicinal Plants – Culinary Herba and Spices, CBS Publisher
10. Thin layer Chromatography – Stahl
11. Phytochemistry and Plant Taxonomy – Bilgrami, CBS Publisher
12. Pharmacognosy – Gokhale, Kokate and Purohit, Nirali Prakashan

M.PHARM. II SEMESTER: PHARMACOGNOSY GROUP

COURSE - III: PLANT BIOTECHNOLOGY

Course Code : PHSG CC -2203 **04hrs/week**

SCOPE

To learn and understand the plant tissue culture, protoplast culture and genetic engineering

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Protoplast culture
- Role of plant growth regulators in plant tissue culture
- Geneti c engineering with special reference to plant cells and micro -organisms

LOCF :

Upon successful completion of the course, the student will be able to:

01	Explain Plant tissue Culture and its importance in micropropagation of medicinal and aromatic plants.
02	Describe the production of phytopharmaceuticals and role of plant growth regulators in tissue culture.
03	Explain isolation of protoplast & haploid protoplast, protoplast fusion and its scope in quality improvement of drug plants.
04	Describe the genetic engineering with special reference to plant cells and micro - organisms.
05	Explain the exogenous and endogenous factors in drug production and Phytogeography & phytogeographical distribution of medicinal plants with special reference to India

Unit -I (12 Hrs):

Plant tissue Culture: Historical perspectives, Types and techniques. Or ganogenesis and embryogenesis, M icro propagation of medicinal and aromatic plants. Nutritional requirement of tissue culture, culture media, growth and metabolism of pl ant tissue culture. Growth parameters of callus and cell culture.

Unit -II (12 Hrs):

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

Biochemical conversions -Application of plant tissue and micro -organisms culture in 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 immobili zation, 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. Mutatio n, Hybridization and diploides Chemodemes and artificial production of mutants .

Unit -V (12 Hrs):

Culture Aspects - Variability in drug activity . Review of exogenous and endogenous factor s in drug production . Soil and plant growth, plant nutrients and thei r role in drug production

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

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

Books Recommended:

1. Pharmacognosy and Phytotherapy: Heinrich, Barnes, Gibbon and Williamson, Publishers: Churchill, Living Stone, London
2. Pharmacognosy – Trease and Eavan, Publisher Elsevier
3. Pharmacognosy, Phytochemistry and Medicinal Plants - Jean Bruneton, Publi sher, Intercept
4. W.H.O. monographs on herbal drug
5. Herbal Medicinal Products – Fruke Geadeke and Brbare Steinholf
6. Phytochemical Methods – Harbone
7. Indian Herbal Pharmacopeia
8. Plant Drug Analysis: A Thin layer Chromatography – Wagner H and Baldts
9. Atlas of Mi croscopy of medicinal Plants – Culinary Herba and Spices, CBS Publisher
10. Thin layer Chromatography – Stahl
11. Phytochemistry and Plant Taxonomy – Bilgrami, CBS Publisher
12. Pharmacognosy – Gokhale, Kokate and Purohit, Nirali Prakashan
13. Pharmaceutical Biotechnolog y – S. P. Vyas and V. K. Dixit , CBC Publisher and Distributer New Delhi
14. Advanced Method in Plant Breeding and Biotechnology – David R. Murray, CAB International Panima Book Distributer
15. Plant Tissue Culture – Dixion , IRL Press Oxford Washington DC
16. Role of Biotechnology in Medicinal and Aromatic Plants Vol. I & II – IA Khan and Atiya Khanum, Ukaoz Publications
17. Plant Chromosome Analysis , Manipulation and Engineering – Arun and Archna Sharma, Harwood Academic Publishers
18. Comprehensive Biotechnology –Murray Moo - Yong, Vol. IV , Pargamon Press Ltd.
19. Pharmaceutical Microbiology – W. B. Hugo and A. D. Russel, IV Ed. , Blackwell Scintific Publication, Oxford, 1987
20. Remington's Pharmaceutical Sciences, Mac Publishing Co. USA

M.PHARM. II SEMESTER: PHA RMACOGNOSY GROUP

COURSE - IV: A DVANCED PHARMACOGNOSY (P)

Course Code : PHSG CC -2204 **16hrs/week**

LOCF

Upon successful completion of the course, the student will be able to:

01	Carry out analytical protocols and preliminary phytochemical screening of crude drugs.
02	Perform experiments based on physico -chemical profiling of herbal materials and formulations.
03	Perform experiments on herbal products and evaluation thereof.
04	Carry out the experiment to develop herbal syrups, mixtures and tablets and their evaluation as per pharmacopeial requirements.
05	Determine and explain the qualitative & quantitative contents of herbal material of medicinal importance.

Practical exerci ses based on the topics mentioned in theory syllabus of

(I) Natural Products

(II) Advanced Pharmacognosy

(III) Plant Biotechnology

Books Recommended:

1. Pharmacognosy – Trease and Eavan, Publisher Elsevier
2. Pharmacognosy, Phytochemistry and Medicinal Plants - Jean Bruneton, Publisher, Intercept
3. Indian Herbal Pharmacopeia
4. Pharmaceutical Biotechnology – S. P. Vyas and V. K. Dixit , CBC Publisher and Distributer New Delhi
5. Advanced Method in Plant Breeding and Biotechnology – David R. Murra y, CAB International Panima Book Distributer
6. Plant Tissue Culture – Dixion , IRL Press Oxford Washington DC

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP

COURSE – I: ADVANCED BIOTECHNOLOGY

Course Code : PHSB CC -2201 **04hrs/week**

SCOPE

To learn and understand the concept of immunology, immunomodulators, and vaccines

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Role of immunomodulators in various pathological conditions
- Methods of vaccine production and quality control
- Antigen -antibody reaction and role of monoclonal antibodies

LOCF :

Upon successful completion of the course, the student will be able to:

01	Describe the immune system and principles of immunology including tumor immunology
02	Explain the immunomodulators and immunologic pathogenesis.
03	Explain the concept of immobilization and monoclonal antibody including hybridoma technology.
04	Describe the various aspects of production of vaccines .
05	Explain the drug delivery aspects of biotechnology products.

Unit -I (1 2 Hrs.) :

Immunology: Principles of disease and epidemology : 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 the ir function. B -cells receptor, B -cell maturation, activation and differentiation, T -cell receptor, its maturation, activation and differentiation. MI - IC- class I & II . MHC and immune responsiveness. Antigen processing and presentation. Immune effector mech anism: Cytokines, The complement system, Inflammation & leukocyte migration. Cell mediated and humoral effector responses. Hypersensitive reactions, immunosuppression, autoimmune disorders, its molecular mechanism, immunodeficiency disorders, tumour immuno logy.

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.

IMMUNOLOGIC PA THOGENESIS: Measures imuunogical features associated with following diseases - Immuno complex allergic disorder , Rheumatic diseases, Drug allergy , Dermatological disorder , Tumor Immunology , Reproduction and Immune System, Eye diseases, Vi ral infection, F ungal infection and Bacterial diseases

Unit -III (1 2 Hrs.)

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

Potentials of immobilized bioactive .

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 vaccin es 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 d rug 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, immobi lization techniques, etc.). Physico - chemical and Physiologic considerations and their significance.

Books recommended :

1. Biotechnology - The Biological Principles: M D Trevan, S Boffey, K H Goulding and P Stanbury
2. Pharmaceutical Biotechnology, S. P. Vyas and V. K. Dixit
3. ImmobiHz;3tion .of Cells and Enzymes: Hosevear kennady cabral & Bicker staff
4. General Microbiology: RY Stainer
5. Essential and applications of microbiology: Judy Kanda!
6. Microbiology: Pelczar, Reid and Chan
7. Molecular Cell Biology: Harvey Lodish, David Baltomore, Arnold Berk, S Lawrence, Paul Matsudaira, James Darnell.
8. Virology: Fields
9. Therapeutic Peptides and Proteins: Formulation, processing and delivery systems: Ajay K Banga
10. Modern Biotechnology: S. B. Primrose
11. Immunology: IWeir
12. Immunol ogy: Ivan Roitt, Johnathan Bronstoff, David Male
13. Medical Microbiology: Mackie and MacCartney
14. Diagnostic Procedures for Viral and Reckettsial Diseases: Lennett & Schmidt

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP

COURSE –II: MOLECULAR B IOLOGY AND GENETIC ENGINEERING

Course Code : PHS B CC -2202 **04hrs/week**

SCOPE

To learn and understand the concept of cell and molecular biology, genetics, genetic disorders and gene therapy

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Regulation of gene activity in prokaryotes and eukaryotes
- Viral and non -viral gene therapy
- Gene therapy of genetic disorders like cystic fibrosis, Thalassaemia, Neuroblastoma, Hepatitis, AI DS, Diabetes, Hemophilia Band SCID

LOCF :

Upon successful completion of the course, the student will be able to:

01 Describe the mechanisms of evolution, growth, development for the improvement of our quality of life. This may be through the development of a drug or drought - resistant crop plant or understanding what controls an individual's health

02 Describe the w orking of cell biologists in the plant and medical science for the development of new vaccines, more effective medicines, plants with improved qualities will also be gathered by the students.

03 Describe the molecular structure of a gene, students will be able to discover ways to control, alter, and replicate the gene — the foundations of genetic engineering. This gene analysis can help identify the molecular basis of phenotypic differences and to select gene expression targets for in -depth study.

04 Descri be the pathophysiology and current status of treatment of different genetic disorders, gene therapy techniques and disorder by altering a person's genetic makeup instead of using drugs or surgery

05 Explain the recombinant DNA (rDNA) technology, gene clon ing , identifying the genetic drivers of a pathology and risk factor s of genetic level.

Unit -I (1 2 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 (1 2 Hrs.):

Cell motility and excitation, cell differentation. 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, m itosis and miosis. Intracellular membrane endoplasmic reticulum and nuclear envelope.

Unit -III (1 2 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 trancsription and processing, translational control, gene rearrangement.

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

Unit -IV (1 2 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, Gen e 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 (1 2 Hrs.):

GENETIC ENGINEERING: Introduction, mutagenisis, cutting and rejoining. Polymerase chain reaction
Isolation and amplification of genes, gene expression and general introduction to genomics.
Genetic recombination : Transfer of characters, genetic recombinatio n, 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.

Books Recommended :

1. Genetics. of Antibiotics Producing Microorganisms: GSe rmonti
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 a nd II, John Wiley Publishers.
11. Biological Reaction Engineering: I J Dunn, E Heinzle, J Ingham, J E Prenosil
12. Cell and molecular biology byVyas S. P. and Mehta A., CBS Publishers and Distributors, New Delhi.
13. Advances in Pharmaceutical Biotechnology Vyas S.P. & Kumar H.D., CBS Publishers New Delhi

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP
COURSE – III : INDUSTRIAL BIOTECHNOLGY

Course Code : PHSB CC -2203 **04hrs/week**

SCOPE

To learn and understand the concept of plant and animal cell culture and fermentation technology

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Principle and application of cell culture techniques
- Fermentation technology
- Design and construction of bioreactors and fermenters

LOCF :

Upon successful completion of the course, the student will be able to:

01	Explain the enzyme technology process, Isolation, preservation and maintenance of industrial enzymes.
02	Describe the Fermentation, Design and construction of fermenter, and Types and control of fermenter.
03	Explain various Fermentation Technology and Industrial fermentation of various desired product.
04	Explain the principles and application of cell culture & prepar ation techniques.
05	Describe potentials of Plant and Animal Cell Culture.

Unit -I (1 2 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 a nd Bioreactors:

Detailed stu dy 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 oxyge n, 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 o f immobilized biocatalyst reactors, bioreactors applications.

Unit -III (1 2 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 (1 2 Hrs.):

Principles o f Cell Culture & Preparation Techniqu es:

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 o f 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 perspective s. Therapeutic novel molecular expression, Trait improvement.

Unit -V (1 2 Hrs.):

Plant a nd Animal Cell Culture:

Types of cultures **:** Callus culture, Meristem -tip culture, organ culture (Flower and fruit organ culture),

microspore and anther culture, protopla st culture, primary culture, continuous culture, cell fusion

micropropagation

Modification through transformative cell culture, Ti -plasmids.

Regenaration of plants. Production of secondary metabolites. Protoplast microinjection.

Mutagenesis technique in pl ant tissue culture.

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

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 Fundaments: Bailey and Ollis
9. Biotechnology of Antibiotics and Other Bioactive Microbial Metabolites: Giancarlo Lancini and Roland Lorenzetii
10. Bioreactor Design and Product Yield: Butterworth and Heinemann
11. Enzyme Assays - A Practical Approach: Robert Eisenthal and Michael J Danson
12. Ferme ntation and Biochemical Engineering Handbook: Henry C Vogel

M.PHARM. II SEMESTER: PHARMACEUTICAL BIOTECHNOLOGY GROUP

COURSE – IV : PHARMA CEUTICAL BIOTECHNOLGY (P)

Course Code : PHSB CC -2204 **16hrs/week**

LOCF :

Upon successful completion of the course, the student will be able to:

01	Perform experiments based on prepar ation of different culture media .
02	Perform experiments based on tissue culture using explants and bacterial culture .
03	Perform experiments based on fermentation process, enzyme isolation, DNA isolation and characterization using various techniques .
04	Perform experiments based on separati on of the components from mixture using chromatographic techniques .
05	Perform experiments based on design of drug delivery system for the delivery of biotechnological products .

Practical exercises based on the topics mentioned in theory syllabus of

(I) Advanced Biotechnology

(II) Molecular biology and Genetic Engineering

(III) Industrial Biotechnology

Books Recommended

1. Therapeutic Peptides and Proteins: Formulation, processing and delivery systems: Ajay K Banga
2. Modern Biotechnology: S. B. Primrose
3. Diagnostic Procedures for Viral and Reckettsial Diseases: Lennett & Schmidt
4. Pharmaceutical Biotechnology -S.P. Vyas, V.K. Dixit 1st ed. CBS Publishers & Distributors, New Delhi, 1998.
5. Current Protocols in Molecular Biology, Vol. I and II: F M Asubel, John Wiley Publishers
6. Current Protocols in Cellular Biology, Vol. I and II, John Wiley Publishers.
7. Advances in Pharmaceutical Biotechnology Vyas S.P. & Kumar H.D., CBS Publishers New Delhi
8. Methods in biotechnology and Bioengineering, By Vyas, S.P. and Kohli, D.V. CBS Publisher s and Distributors, New Delhi
9. Pharmaceutical Biochemistry, Vyas& Kohli
10. Industrial Biotechnology: L E Casida
11. Industrial Biotechnology: Vedpal S Malik and Padma Sridhar
12. Animal Cell Culture: Ian Freshney
13. Bioreactor Design and Product Yield: Butterworth and He inemann
14. Enzyme Assays - A Practical Approach: Robert Eisenthal and Michael J Danson

M.PHARM. III SEMESTER

COURSE – ELECTIVE – I : COSMETICOLOGY

Course Code : PHSE C -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 cosm etics. 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.

Un it -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

Un it -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 RJ. 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 a nd 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.PHA RM. III SEMESTER

COURSE – ELECTIVE – II : IM MUNOLOGY AND IMMUNOASSAYS

Course Code : PHS EC -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 Immunolobulines.
The humoral immune response
The cellular immune response
The control of immune response
The complement system

Unit -II (09 Hrs.):

Pharmacological aspects of clinical cond itions involving immunologial mechanism:
a) Hypersensitivity
b) Delayed hypersensitivity
c) Immunnomodulators

Unit -III (09 Hrs.)

Current concepts in therapy and research of drugs for:

a) Acquired Immuno Deficiency Syndrome (AIDS)
b) Tissue transplantation (Immunosuppresants and imrnunoenhancers)
c) Cancer
d) Vaccines and sera
e) Antifertility drugs and vaccin
f) Drug allergy
g) Methods for (invitro and invivo) evaluation of influencing immune system drugs.
h) Biochemical tests used in immunology laboratory.

Unit -IV (09 Hrs .)

Radioimmassays (RIA): Enzyme multiplied Immuno assay techniques (EMIT)
Fluoroscence polarization Immunoassay (FPIA)
Enzyme linked Immunosorbent Assay (ELISA)
Apoenzyme - Reactivation Immunoassay (NIIA)
Substrate labeled flouroscence 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, Fc8R family, Proteins, transcripts and genes: Gene, structure and actions of high affinity. Fc receptor for immunoglobulin E. binding factors. E .

Fc - receptor mediated kill ing.

Fc – receptor on T and B lymphocytes

Immunoglobulin binding factors

Books Recommended :

1. Kirkwood E and Catriona L. 'Understanding Medical immunology (Jobn Wiley and Sons New Yard)
2. Humphrey J.H. and White RG. Immunology for students of medicines (Blac kwell Scientific Publication London)
3. Goodman and Gilmans. The pharmacological Basis of therapeutics (9th Ed.) McGraw Hill, 1996)

M.PHARM. III SEMESTER

COURSE – ELECTIVE - III : PHYTOPHARMACEUTICALS AND NUTRACEUTICALS

Course Code : PHS EC -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 bili ary 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):

Phytopharmacueuticals it therapeutic usage. Source, phyto -chemistry and physiological activities of Taxol, Camptothecin, podophyllotoxin, Genistein, Hypericin, Valepotraits, Ginkoside, Colenol, 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

Books Recommended:

1. Pharmacognosy and Phytotherapy: Heinrich, Barnes, Gibbon and Willamson – Churchil, 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 Medic al Products, Dr. Fruke Gaedeke and Dr. Brbare Steinholf

M.PHARM. III SEMESTER

COURSE – ELECTIVE -IV : ADVANCED PHARMACEUTICAL CHEMISTRY

Course Code : PHS EC -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. 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 antiinflamatory drugs. Agents used in neurodegerative disorders like Alzheimer and Parkinson. Drugs binding to nucleic acid –antimalarial, Anticancer an d Antiviral.

Unit -III (09 Hrs.):

Protein and Peptide drugs: Chemsitry, structure and stability, Different ways to synthesize, Study of Insulin, Relaxin, Somatostatin, DNAase, Interferon.
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 precur sors for biosynthesis of some selected heterocyclic and nonheterocyclic alkaloids.

Books recommended:

1. Organic chemistry YoUI by 1.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