

UNIVERSITY OF MUMBAI

No.UG 319 of 2004

CIRCULAR :

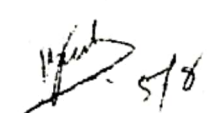
Attention of the Director, Mumbai University Institute of Chemical Technology and the Principals of affiliated colleges in Pharmacy is hereby invited to the Ordinances, Regulations and Syllabi relating to the Master of Pharmaceutical Sciences (M. Pharm. Science) degree course vide Pamphlet No.198 and to this office Circular No. UG/228 of 2002 dated 21st May, 2002 and they are hereby informed that the recommendations made by the Board of Studies in Pharmaceutical Sciences at its meeting held on 21st April, 2004 has been accepted by the Academic council at its meeting held on 18th June, 2004 vide item No. 4.11 and that in accordance therewith the following specializations have been introduced under the M.Pharm. Science degree course :-

- (i) Medicinal Chemistry
- (ii) Drug Delivery Technology
- (iii) Pharmaceutical Biotechnology

Further that the syllabi for the above specializations is as per Appendix and that the same has been introduced with effect from the academic year 2004-2005.

Mumbai 400 032

5th August, 2004


for I/c REGISTRAR

To,

The Director, Mumbai University Institute of Chemical Technology and the Principals of the affiliated colleges in Pharmacy.

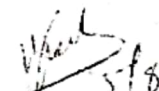
I.C. No. 411/18.06.2004

No UG 319-A of 2004

5th August, 2004.

Copy forwarded with Compliments for to :-

- 1) The Dean, Faculty of Technology.
 - 2) The Chairman, Ad-hoc Board of Studies in Pharmaceutical Science.
- for information.


for I/c REGISTRAR
P.T.O.

UNIVERSITY OF MUMBAI



Syllabus for M. Pharm. Science Degree Course

- (i) Medicinal Chemistry
- (ii) Drug Delivery Technology
- (iii) Pharmaceutical Biotechnology

(with effect from the academic year 2004-2005)

Core Subject: Advanced Organic Chemistry I

No	Content	Hrs
1	Oxidation-reduction reactions: Oxidations using permanganate, chromic acid and chromyl compounds, vanadium, osmium, cobalt(III), cerium(IV), lead tetracetate, with mechanisms and suitable examples. Reductions using metal in alcohol/ammonia, metal hydrides, metal amalgams, isopropoxide in alcohol, metal and acid/alkali with mechanisms and suitable examples.	10
2	Organometallics: Formation of C-C bonds, organometallics reagents and catalysts, mechanisms of catalysis, reactivity of catalysts, organometallic reagents involving magnesium, sodium, lithium, copper, cadmium, zinc, nickel, palladium, cobalt and rhodium.	10
3	Catalysis: Heterogenous catalysis- mechanisms and important catalysts, stereoselective catalysis, homogenous catalysis, phase transfer catalysts, metals in complexed and polymer based catalysts.	5
4	Asymmetric synthesis: Chiral synthesis using chiral pool, chiral auxiliary, chiral catalysts, enzymes, chiral solvents, and whole organisms. Analytical methods of determining purity of stereoisomers.	5
	Total	30

Books:-

1. Kenneth B Wiberg, Oxidations in Organic Chemistry, Academic Press, 1965
2. Bader F, Reaction Mechanism in Organic Chemistry, Abacus Press, Turnbridge Wells, Kent, 1977
3. Norman R.D.C, Principles of Organic Synthesis, Chapman and Hall, London, 1978
4. Carey F. A and Sundberg, R.J., Advanced Organic Chemistry, 4th Ed., Parts A and B, Kluwer Academic /Plenum Publishers, New York, 2001
5. Blackburn D. W., Catalysis of Organic Reactions, Marcel Decker Inc., N. Y., 1990.
6. Delannay F, Characterization of Heterogenous Catalysis
7. Kosak J. R., Catalysis of Organic Reactions
8. Augustine, R.L., Catalysis of Organic Reactions
9. Aitken R.A., Kilenyi S. N., Asymmetric Synthesis, Chapman and Hall, London, 1994
10. Sheldon R.A., Chirotechnolgy, industrial synthesis of optically active compounds, Marcel Decker, N.Y., 1993
11. Krogsgaard-Larsen P, Liljefors, T, Madsen U, Textbook of Drug Design and Discovery, 3rd Ed., Taylor & Francis, London, 2002.
12. March J., Advanced Organic Chemistry, John Wiley and Sons

M. Pharm. Syllabus

Branch – Medicinal Chemistry

The new M. Pharm specialization in Medicinal Chemistry will have 5 papers in the first semester and 4 papers in the second semester

in addition in Semester II, each student will deliver a seminar on a topic given by the respective research guides. The core subjects are compulsory and remaining papers will be taken from the list of electives. Each paper will be of 50 marks.

Following is the list of core subjects and electives to be offered in Semesters I and II.

Semester I – Core Subjects

1. Advanced Organic Chemistry I
2. Advanced Biochemistry
3. Spectroscopy I

Semester II – Core Subjects

4. Advanced Organic Chemistry II
5. Drug Metabolism

Electives

1. Drug Design
2. Spectroscopy II
3. Enzymology
4. Receptorology
5. Molecular Biology
6. Biostatistics
7. Separation Techniques

Core Subject: Advanced Biochemistry

No	Content	Hrs
1	Proteins: Structures – primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies	4
2	Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca^{+2} and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage	4
3	Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing.	4
4	Protein biosynthesis: Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.	4
5	DNA and nucleic acids: DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms.	6
6	Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.	4
7	Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids	4
Total		30

Books:

1. Lehninger Principles of Biochemistry by Lehninger and Nelson D. L.; C.B.S. Publishers and Distributors-Delhi, 2000.
2. Biochemistry by Stryer L.; W.H. Freymont & Co.-New York, 1995.
3. Molecular Cell Biology by Lodish H. and Darnay J.; Scientific American Books-New York, 2004.

Core Subject: Spectroscopy I

No	Content	Hrs
1	Problems in structure determination using an integrated approach	
2	Application of UV in structure determination	2
3	Application of IR in structure determination	2
4	Application of NMR in structure determination	8
5	Application of MS in structure determination	4
6	Problems based on the integrated approach of the four spectroscopic techniques of UV, IR, NMR and MS.	14
	Total	30

Books:

1. Applications of Absorption Spectroscopy of Organic Compounds, John R Dyer, Prentice Hall, India, 1984.
2. Organic Structural Spectroscopy, Lambert, J.B., Shurvell H.F., Lightner D.A. and Cooks R.G., Prentice Hall, New Jersey, 1998.
3. Structure Elucidation by Modern NMR, Duddeck H. and Dietrich W., Steinkopf Verlag, Darmstadt Germany, 1989.
4. Mass Spectrometry, Principles and Applications, Williams D.H. and Bowen R.D., 2nd Ed., McGraw-Hill Book Co., London, 1981.

Core Subject: Advanced Organic Chemistry II

No	Content	Hrs
1	Combinatorial chemistry: Introduction, advantages, planning combinatorial reactions, solid phase and solution synthesis, supports for combinatorial synthesis, linkers, tag reagents, radiofrequency tags, deconvolution and iteration, parallel synthesis, multistep – convergent and sequential synthesis, multicomponent reactions.	15
2	Synthon approach: Dissection of molecules, retrosynthesis and its advantages, various synthons and their synthesis, applications of synthon approach to synthesis of selected chemical compounds.	10
3	Protective Groups in Organic synthesis: Protective groups for hydroxyl, amino, carbonyl, carboxyl and thiol. Synthetic equivalent groups. Protection and deprotection concepts. Selected applications.	5
	Total	30

Books:

1. Carey F. A and Sundberg R.J. Advanced Organic Chemistry, Parts A and B, Plenum Press, 2001
2. Wilson S. R. and Czamik A, Combinatorial Chemistry: Synthesis and Applications, John Wiley & Sons, N. Y. 1997.
3. Fox M.A., Organic Chemistry, J.K. Whitesell Jones & Bartlett Publications, 1994
4. Corey E.J., Retrosynthesis
5. Warren S, Organic Synthesis, The disconnection Approach, John Wiley & Sons, 1982.
6. Iyer R.P and Prabhu A. V., Synthon Approach
7. Handbook of Combinatorial chemistry: drugs, catalysts, made by Nicolaou K. C. and Hanno R.; Weinheim Wiley-Vch Verlag-Hartwig-2002.

Core Subject: Drug Metabolism

No	Content	Hrs
1	Introduction to the different pathways of drug metabolism: Phase I and II reactions, sites of drug metabolism, subcellular localization of drug metabolizing enzymes, cofactors required for catalytic reactions	7
2	Cytochrome P450 oxidative system: Catalytic cycle of P450 reactions, mechanism of P450 hydroxylation reactions, introduction to CYP450 superfamily of enzymes and their classification, human CYP450s involved in drug metabolism and their typical substrates, inhibitors and inducers.	7
3	Introduction to other drug metabolism enzyme isoforms/families: Glucuronosyltransferases, glutathione transferases, sulfotransferases, N-acetyltransferases, FMO's.	10
4	Methods for studying drug metabolism: Isolated enzymes, recombinant enzymes, subcellular fractions, hepatocytes, perfused liver, in-vivo drug metabolism studies – introduction to these methods, their utility, advantages and limitations.	4
5	Introduction to in-silico methods for predicting drug metabolism: Principles behind development of these systems, their potential and their limitations.	2
Total		30

Books:

1. Foye's Principles of Medicinal Chemistry, William D.A and Lemke T.L., 5th Edition, Lippincott Williams and Wilkins, 2002
2. Handbook of Drug Metabolism, Woolf T.F., Marcel Dekker Inc., 1999.
3. Drug Metabolising Enzymes, Lee J.S., Obach S.R., Fisher M.B., Funtis Media S.A., 2003
4. Cassaret and Doull's Toxicology, The Basic Science of Poisons, Klaasen C. D., Amdur M.O., and Adull J., 5th Ed., McGraw Hill, N.Y., 1996
5. Fundamentals of Drug Metabolism and Disposition, La Du B.N., Mandel H.L., & Way L.E., 1st Ed., Waverly Press, Baltimore, 1972.

Elective: Drug Design

No	Content	Hrs
1	Sources of drugs/leads: Serendipity, random screening, natural sources, molecular modification; Lead optimization; Rational drug design	2
2	Molecular Mechanics : General features of force fields, cross terms, forcefield parametrization; Energy minimization – non-derivative and derivative methods, applications of energy minimization; Techniques of searching the conformational space – systematic search, Monte Carlo, Molecular dynamics and distance geometry	8
3	Docking by: Energy minimization; Superimposition; Molecular dynamics; Metropolis Monte Carlo; Monte Carlo minimization; Genetic algorithms; Distance geometry; Build up approach; Egs from literature and programs available	4
4	De Novo ligand design: Classes of De Novo ligand design – active site analysis methods, whole-molecule methods, connection methods, random connection and disconnection methods; Egs from literature and programs available.	3
5	Pharmacophore modeling: Difficulties in deriving a 3D-pharmacophore; Techniques – constrained systematic search, ensemble distance geometry, ensemble molecular dynamics and genetic algorithms; Incorporating additional geometric features into a 3D pharmacophore; 3D database searches for pharmacophores	3
6	QSAR: History and development of QSAR; Parameters – lipophilicity and related parameters, electronic parameters, steric parameters, other parameters; Quantitative models. – Hansch approach, Free Wilson analysis, the mixed approach; Statistical methods – regression analysis, partial least square and other multivariate statistical methods; Design of test series in QSAR; Some examples of Hansch and other methods; 3D-QSAR approaches – CoMFA and CoMSIA, brief discussion on other methods like MSA, RSA and HASL methods	10
	Total	30

Books:

1. 3D QSAR in Drug Design: Theory, Methods and Applications, Kubinyi H Ed., Leiden ESCOM, 1993.
2. Molecular Modelling – Principles and Applications, Andrew R Leach, 2nd Ed., Prentice Hall, 2001.
3. Practical Application of Computer-Aided Drug Design, Paul S Charifson, Ed., Marcel Dekker, Inc., 1997.
4. Reviews in Computational Chemistry, Lipkowitz K.B. and Boyd D.B. Eds, VCH Publishers, N.Y.
5. Comprehensive Medicinal Chemistry, Series Ed. Hansch C., Vols 1-5, Pergamon Press.
6. Burgers Medicinal Chemistry, Vol.1 -5.

Elective: Spectroscopy II

No	Content	Hrs
1	Nuclear Magnetic Resonance Spectroscopy: Pulsed experiments, factors influencing chemical shift, coupling constant, spin-lattice and spin-spin relaxation, multiple resonance, nuclear Overhauser effect, spectral editing, sensitivity enhancement, phase cycling and composite pulses; Two-dimensional NMR, Proton-proton correlation through coupling, proton-heteronuclear correlation, proton-proton correlation through space of chemical exchange, carbon-carbon correlation, higher dimensions, pulsed field gradients.	15
2	Mass Spectrometry: Ionization – EI, CI, DI, MALDI, SI and ESI; Mass analysis – TOF analysers, quadrupole mass filters, ion cyclotron resonance, tandem mass spectrometers; General principles of fragmentation – energetics of dissociation, odd- and even- electron ions, Stevenson's rules, rearrangement vs simple cleavage, proximate vs remote fragmentation, distonic ions, charge localization, characteristic fragment ions and neutral fragments; Chemical analysis – molecular weight determination, molecular structure determination, molecular formula determination; Isotopic analysis, quantitative analysis, mixture analysis- chromatography-mass spectrometry, tandem mass spectrometry (MS-MS), thermochemical determinations.	15
Total		30

Books:

1. Organic Structural Spectroscopy, Lambert, J.B., Shurvell H.F., Lightner D.A. and Cooks R.G., Prentice Hall, New Jersey, 1998.
2. Structure Elucidation by Modern NMR, Duddeck H. and Dietrich W., Steinkopf Verlag, Darmstadt Germany, 1989.
3. Modern NMR Techniques, Derome A.E., Pergamon Press, Oxford, UK, 1987
4. Mass Spectrometry, Principles and Applications, Williams D.H. and Bowen R.D., 2nd Ed., McGraw-Hill Book Co., London, 1981.

Elective: Enzymology

No	Content	Hrs
1	Structure and Classification: Primary structure, 3D-structure, quaternary structure, folding and domains, ribozymes, nomenclature and classification of enzymes	4
2	Catalytic activity of enzymes: Enzyme kinetics, Michaelis Menten kinetics, IC_{50} values, specificity of enzymes (active sites), energetics and binding energies – Thermodynamics, molecular fit, allosteric sites	4
3	Enzyme Inhibition: Reversible enzyme inhibitors – competitive, non-competitive, uncompetitive with kinetics, slow and tight binding enzymes, transition state inhibitors, multisubstrate analogs, irreversible enzyme inhibitors, k-cat inhibitors (suicide substrates)	8
4	Drugs acting by enzyme inhibition: Protease inhibitors – ace inhibitors and renin inhibitors, reductase inhibitors – HMG-Co reductase inhibitors, HIV-reverse transcriptase, protease and integrase inhibitors, cyclooxygenase, leukotrienes and lipoxygenase inhibitors, aromatase inhibitors and DHFR inhibitors.	6
5	Rational drug design of enzyme inhibitors: Two to three case studies with inputs from molecular drug design/combinatorial chemistry.	4
6	Enzymes as biocatalysts – an introduction: Types of enzymes commonly used, organic biocatalysis and stereochemistry, enzyme immobilization, industrial applications.	4
Total		30

Books:

1. Enzymes, Dixon M and Webb E. C., 3rd Ed., Longman Group Ltd., 1979.
2. Burgers Medicinal Chemistry, Vol. 1.
3. Lehninger, Principles of Biochemistry, Nelson D. L. & Cox M.M., 3rd Ed., Replika Press Pvt. Ltd., India, 2000
4. Biochemistry, Stryer L, 3rd Ed. W.H. Freeman & Co., N.Y., 1988.
5. Handbook of Drug Screening, Seethala R & Fernandes P.B., No. 114, Drug and Pharmaceutical Sciences – A series of Textbooks and Monographs, Marcel Dekker, N.Y. and Basel, 2001.
6. A Textbook of Drug Design and Development, Krogsgaard-Larsen P, Liljefors T & Madsen U., 2nd Ed., Harwood Academic Publishers.

Elective: Receptorology

No	Content	Hrs
1	Receptor and Enzyme concepts	1
2	Receptor Theory: Basic ligand concepts – potency, efficacy, agonists, antagonists, inverse agonist, partial agonist, pharmacological vs functional antagonism; Receptor theories – occupancy model, rate theory, inactivation theory	2
3	Second and third messenger system	7
4	Molecular biology of receptors: Receptor cloning and strategies; Sequence analysis of cloned receptors; Expression of cloned receptors; Structural analysis of cloned receptors	4
5	Receptor Binding Assays: Binding definitions, membrane receptor assay, radioligand issues, receptor source, separation techniques, data analysis	4
6	Receptor Classification	3
7	3D structure of adrenergic, cholinergic, histamine and dopamine receptors with emphasis on functional mapping of ligand binding sites.	8
Total		30

Books:

1. Cell Surface Receptors : A Short Course on Theory and Methods, Limbird, L.E., Nijhoff, Boston, 1986.
2. Drug Development, Hanmer C. E., Ed., 2nd Ed., CRC Press, Boca Raton, 1990.
3. Pharmacologic Analysis of Drug-Receptor Interaction, Kenakin, T.P., Raven, N.Y., 1987.
4. Principles in General Pharmacology, Tallarida, R.J., Raffa, R.B. and McGonigle P., Springer-Verlag, N.Y., 1988.
5. Receptor Pharmacology and Function, Williams, M., Glennon, R.A. and Timmermans P.B.M.W.M, Eds, Marcel Dekker, N.Y., 1988.

Elective: Molecular Biology

No	Content	Hrs
1	Introduction to recombinant DNA technology: Introduction to DNA and its functions, Replication of DNA and its transcription and translation, restriction enzymes and their properties, vectors for use in rDNA technology, creation and introduction of rDNA molecules, cloning and expression of rDNA molecules, cloning and expression systems, their advantages and limitations, application of rDNA technology in production of pharmaceutical and in drug discovery and development.	14
2	High throughput screening: Introduction to the principles of screening and the philosophy of HTS, considerations in HTS method development, validation of HTS methodology, some examples of typical HTS assays and the principles involved therein.	4
3	Genomics/Proteomics: Introduction to the definitions of various 'omics', introduction to the general field of genomics and proteomics, introduction to some methods used in analyzing gene expression at the mRNA and protein level, basic principles of DNA/Protein microarrays and their applications.	6
4	Human Genome Initiative: Introduction to the genome, genome complexity and genome organization, basic approaches towards sequencing of genomes, the approach for sequencing the human genome, sources for obtaining human genome sequence information, data mining of the human genome sequence for information and other potential applications, introduction to bioinformatics.	6
Total		30

Books:

1. Molecular Biotechnology, Principles and Applications of recombinant DNA, Glick B. R. & Pasternak J.J., 3rd Ed. ASM Press, Washington D.C., 2003
2. Principles of Genome Analysis & Genomics, Primrose S.B. & Twyman R.M., 3rd Ed., Blackwell Publishing, U.K., 2003
3. Gene Biotechnology, Jogdand S.N., Himalaya Publishing House, 2003
4. Biotechnology-Theory & Techniques, Gen Engg, Mutagenesis, Separation Technology, Chirirjian J G, Jones & Bartlett Publishers, 1995.
5. Pharmaceutical Biotechnology – A introduction for Pharmacists & Pharmaceutical Scientists, Crommelin D.A. & Sindelar R. D., Harwood Academic Publishers, 1997.

Elective: Biostatistics

No	Content	Hrs
1	Collection and organization of data: Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.	3
2	Probability : Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, probit and logit analysis.	5
3	Regression : Linear regression and correlation, curvilinear regression, method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.	8
4	Parametric tests: Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients	5
5	Nonparametric tests: Data characteristics and nonparametric procedures, chi square test, sign test, Wilcoxon sign rank test, goodness of fit test, Mann-Whitney etc.	4
6	Experimental designs: Randomization, completely randomized and latin square designs, factorial design, cross over and parallel designs.	5
Total		30

Books:

1. Pharmaceutical Statistics – Practical and Clinical Applications, Sanford Bolton, 3rd Ed., Marcel Dekker, Inc., N.Y., 1997.
2. Biostatistics: A Foundation for Analysis in the Health Sciences, Wayne W Daniel, 3rd Ed., John Wiley & Sons, Inc., 1983.
3. Introduction to Statistical Analysis, Dixon W.J. and Massey F.J., 3rd Ed., McGraw-Hill, N.Y., 1969.
4. Statistical Methods, Snedecor G.W. and Cochran W.G., 8th Ed., Iowa State University Press, Ames, Iowa, 1989.

Elective: Separation Techniques

No	Content	Hrs
1	Column Chromatography – merits and demerits, short column chromatography, flash chromatography, medium pressure liquid chromatography, high pressure liquid chromatography, centrifugal chromatography, TLC, HPTLC, normal and reverse phase chromatography	15
2	Counter-current chromatography, droplet counter-current chromatography, solvent systems, ion-exchange, affinity, size exclusion, cation/anion exchange, gel electrophoresis for proteins and DNA	15
	Total	30

Books:

1. Dynamics of Chromatography by Giddings J.C.; Marcel Dekker Inc.-New York, 1965.
2. Protein Purification Principles and Practice by Scoopes R. K.; Springer Verlag- New York, 2nd Edition, 1987.
3. Practicals of High Performance Liquid Chromatography: Applications Qualitative and Quantitative analysis by Eryelhardt H.; Springer-Verlag- Berlin-1986.
4. Chromatographic methods by Stock R. and Rice C. B. F.; Chapman & Hall Ltd.-London, 3rd Edition-1974.
5. Modern Advances in chromatography by Freiteg R.; Springer-Berlin,2002.

Branch: Pharmaceutical Biotechnology

Semester I – Core Subjects

1. Advanced Biochemistry
2. Molecular Biology
3. Fermentation Technology

Semester II – Core Subjects

4. Production and Control of Biotechnology derived products
5. Analytical methods for Biotech products

Electives

1. Advanced Immunology
2. Plant Cell culture and Mammalian cell culture
3. Microbial and Enzyme biotransformation

Core Subject: Advanced Biochemistry

No	Content	Hrs
1	Proteins: Structures –primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies	4
2	Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca^{+2} and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage	4
3	Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing.	4
4	Protein biosynthesis: Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.	4
5	DNA and nucleic acids: DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms.	6
6	Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.	4
7	Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids	4
Total		30

Books:

1. Lehninger Principles of Biochemistry by Lehninger and Nelson D. L.; C.B.S. Publishers and Distributors-Delhi, 2000.
2. Biochemistry by Stryer L.; W.H. Freymont & Co.-New York, 1995.
3. Molecular Cell Biology by Lodish H. and Darneu J.; Scientific American Books-New York, 2004.

Core Subject: Molecular Biology

No	Content	Hrs
1	Introduction to biological macromolecules	4
2	DNA replication, transcription, gene splicing, gene cloning, gene expression	4
3	Genotype and Phenotype variation of characters and microbes	4
4	Genetic organization of prokaryotic and eukaryotic cells	4
5	Protein biosynthesis and regulation (Induction, repression of enzymes, catabolic repression)	6
6	Methods of alteration of genetic apparatus (Genes)(Mutation, transition, recombination, protoplast fusion)	4
7	Proteomic, Genomics	4
	Total	30

Books:

1. Molecular Biotechnology, Principles and Applications of recombinant DNA, Glick B. R. & Pasternak J.J., 3rd Ed. ASM Press, Washington D.C., 2003
2. Principles of Genome Analysis & Genomics, Primrose S.B. & Twyman R.M., 3rd Ed., Blackwell Publishing, U.K., 2003
3. Gene Biotechnology, Jogdand S.N., Himalaya Publishing House, 2003
4. Biotechnology-Theory & Techniques, Gen Engg, Mutagenesis, Separation Technology, Chirirjian J G, Jones & Bartlett Publishers, 1995.
5. Pharmaceutical Biotechnology - A introduction for Pharmacists & Pharmaceutical Scientists, Crommelin D.A. & Sindelar R. D., Harwood Academic Publishers, 1997.

Core Subject: Fermentation Technology

No	Content	Hrs
1	Definition of Fermentation-Batch, Fed State and Continuous fermentation	4
2	Role of Bioengineering in fermentation (Geometry of fermentation, designing of impellers, agitation systems and environmental conditions of fermentation)	4
3	Fermentative production of important secondary metabolites eg. Penicillins, streptomycin, gentamycin, polyene, polyene macrolides, macrolides, anthracyclines	4
4	Principles of Downstream processing fermentation products	4
5	Unit operations and techniques employed in downstream processing of fermentation products	10
6	Microbial strain selection and preservation methods	4
	Total	30

Books:

1. Biotechnology Comprehensive Series, @nd Edition, Editors: H.J. Rehm, and G. Reed.
2. Encyclopedia of bioprocess technology, Michale C. Flickinger

Core Subject: Production and Control of Biotech Derived Products

No	Content	Hrs
1	Recombinant DNA products (Insulin, Growth hormones, Erythropoietin cytokines)	5
2	Definition, general methods procedures for preparation of DNA products	5
3	Quality control testing methods of Biotech products	5
4	Determining impurities / contamination (Viral, bacterial endotoxins in <i>vitro</i>) rabbit pyrogen, sterility, protein, identification finger prints by electrophoresis, ISO electric focusing, immunogenicity, partial sequential analysis	7
5	General requirements for the production of R-DNA products	3
6	Containment measures, environment and safety issues	3
7	Hazards associated with R-DNA products	2
	Total	30

Books:

1. Biotechnology Comprehensive Series, 2nd Edition, Editors: H.J. Rehm, and G. Reed.
2. Encyclopedia of bioprocess technology, Michale C. Flickinger

Core Subject: Analytical methods for Biotech products

No	Content	Hrs.
1	Chromatography (TLC, HPTLC, HPLC, GC), special emphasis on Protein separation-Electrophoresis, Gel Electrophoresis,	10
2	1D, 2D, size exclusion and ion Exchange chromatography,	10
3	Affinity chromatography	10
	Total	30

Books:

1. Commercial biotechnology an international analysis,
2. Biotechnology Comprehensive Series, @nd Edition, Editors: H.J. Rehm, and G. Reed.
3. Encyclopedia of bioprocess technology, Michale C. Flickinger

Elective: Advanced Immunology

No	Content	Hrs.
1	Introduction to Immune system , Immune response,	10
2	Monoclonal antibodies and diagnostics using monoclonal antibodies,	10
3	Vaccines	10
	Total	30

Books:

1. Immunology, P.M. Lydyard, A. Whelan, M.W. Fanger
2. Fundamental of immunology, Weiser R.S.
3. Basic and clinical immunology, Fudenberg H.H
4. Microbiology with virology and immunology, Pyatkin K.D.

Elective: Plant cell culture and Mammalian cell culture

No	Content	Hrs.
1	Laboratory organization for tissue culture, classification of tissue culture,	5
2	Tissue (Callus) culture techniques, Culture techniques ,	10
3	Subculture and preservation of cultures, suspension culture techniques, isolation of protoplast, Aspects of organization,	10
4	Plant tissue culture achievements and prospects, collection, storage and exchange of germ plasma.	5
	Total	30

Books:

1. Trends in plant cell culture and biotechnology, Pareek L.K.
2. A text book of biotechnology, Kumar H.D
3. Molecular cloning, Sambrook
4. Recent advances in biotechnological application in biotechnology of plant cell and tissue culture, Ravishankar G.B.
5. Cell and tissue culture: lab. Production in biotechnology, Doyle A.

Elective: Microbial and Enzyme biotransformation

No	Content	Hrs.
1	Techniques of immobilization	10
2	Immobilized enzyme systems, immobilized whole cells	10
3	Technological aspects of bioconversion	10
	Total	30

Books:

1. Biotransformation in organic chemistry, Faber Kurt
2. Enzyme in Industry, Wolfgang Gerhards
3. Microbial and enzymatic Biotechnology, Fogarty W.M.
4. Bioreactor and Biotransformation, Moody G.W. and Baker P.B.

Branch – Drug Delivery Technology

Semester I -Core Subjects

1. Drug Delivery Systems – I
2. Biopharmaceutics and Pharmacokinetics
3. Advanced Pharmaceutical Analysis

Semester II - Core Subjects

4. Drug Delivery Systems – II
5. Models for Drug Delivery Systems evaluation

(Syllabus for Core Subjects 2 and 3 are same as in the present M.Pharm.Sc Syllabus)

Electives :

1. Pharmaceutical Biotechnology
2. Herbal Drug Development and Standardization
3. Intellectual Property Rights and Patent Filing
4. Therapeutic Drug Monitoring
5. Polymers in Pharmaceuticals
6. Technology of Cosmetics
7. Instrumental Techniques for Drug Delivery Systems Characterization
8. Validation and Regulatory Compliance

(Syllabus for Electives 1 to 6 are same as in the present M.Pharm.Sc Syllabus)

Core Subject : Drug Delivery Systems – I

No	Content	Hrs
1	Design, development, manufacture and evaluation of the following:	
2	Oral Drug Delivery Systems : Osmotic DDS, Ionexchange controlled DDS, Hydrodynamically balanced DDS, Pulsatile DDS including recent advances	8
3	Mucosal DDS : Physiological basis of mucosal delivery with reference to oral mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration.	7
4	Transdermal DDS : Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to manufacturing equipment components and evaluation. Iontophoretic and Sonophoretic DDS.	7
5	Ocular DDS – Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.	3
6	Intrauterine DDS – Medicated and non-medicated IUD's	1
7	Dental DDS : DDS for oral conditions, and dental care and therapy including periodontal disease, dental caries etc.	2
8	Veterinary DDS – Physiological basis, devices and formulations	2
	Total	30

Books

1. Handbook of Pharmaceutical Controlled Release Technology, edited by Donald Wise Marcel Dekker, 2000.
2. Oral Mucosal Drug Delivery by Michael J. Rathbone (Editor) Marcel Dekker; (June 1996)
3. Bioadhesive Drug Delivery Systems Fundamentals, Novel Approaches, and Development Series Volume: 98 Edited By: Edith Mathiowitz; Don E. Chickering; Claus-Michael Lehr 1999.
4. Nasal Systematic Drug Delivery Series Volume: 39 Yie W. Chien; Kenneth S.E. Su; Shyi-Feu Chang 1989.
5. Transdermal Drug Delivery by Richard H. Guy (Editor), Jonathan Hadgraft (Editor), Michiko Elizabeth Barro Yusa Marcel Dekker; 2nd edition (January 2003)
6. Electrically Assisted Transdermal and Topical Drug Delivery by Ajay K. Banga, Taylor & Francis; (September 1998)
7. Mechanisms of Transdermal Drug Delivery Volume: 83 Edited By: Russell O. Potts; Richard H. Guy. 1997
8. Transdermal Controlled Systemic medications by Y. W. Chien, Marcel Dekker, 1987
9. Biopharmaceutics of Ocular Drug Delivery by Peter Edman CRC Press; (November 18, 1992)
10. Ophthalmic Drug Delivery Systems, edited by Ashim Mitra, Marcel Dekker, 1993.
11. Novel Drug Delivery Systems Second Edition, Revised and Expanded Series Volume: 50 Yie W. Chien, 1991.
12. Controlled Release Veterinary Drug Delivery by Michael J. Rathbone (Editor), Robert Gurny (Editor) Elsevier Science; 1st edition (July 1, 2000)
13. Polymeric Drugs & Drug Delivery Systems Raphael M. Ottenbrite and Sung Wan Kim, eds Technomic, 2001.
14. Controlled Drug Delivery – Foudamentals & applications by J.R. Robinson-2nd edition - Marcel Dekker, 1987
15. Dermatological Formulations : Percutaneous absorption by Brian W. Barry.

Core Subject : Drug Delivery Systems – II

No	Content	Hrs
1	Design, development, manufacture and evaluation of the following:	
2	Parenteral DDS : CR injectables, implants etc. development and evaluation	5
3	Colloidal DDS : Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, sub micron emulsions, liposomes, niosomes, and other vesicular DDS, nanoparticles, their design and development into final dosage forms, issues and consideration	8
4	Peptide and protein based DDS : Chemistry and special features of peptide and protein molecules, stability, analysis. Formulation and evaluation Barriers to peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS.	5
5	Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurised aerosols, Dry powder DDS, Devices for administration and evaluation.	4
6	Targetted DDS : Concept of drug targeting, basis for drug targeting both active and passive. Monoclonal antibodies and other markers, design of targeted DDS.	4
7	Stimuli sensitive DDS – Basis and Need, smart polymers for DDS, feedback regulated systems.	2
8	Miscellaneous DDS : DDS for orthopaedic applications Intracoronary stents. (medicated and non-medicated)	2
	Total	30

Books

1. Sterile Dosage Forms: Their Preparation and Clinical Application by Salvatore J., M.S. Turco, Salvatore Turco Lea & Febiger; 4th edition (January 1994)
2. Parenteral Quality Control Sterility, Pyrogen, Particulate, and Package Integrity Testing: Third Edition, Revised and Expanded Series Volume: 125 Michael J. Akers; Dan Larrimore; Dana Morton Guazzo 2002.
3. Colloidal Drug Delivery Systems by Jorg Kreuter (Editor) Marcel Dekker; 1st edition (July 15, 1994).
4. Controlled Release Gel Formulations for Mucosal Drug Delivery edited by Mattias Paulsson Uppsala Universitet; (December 2001)
5. Colloidal carriers for controlled drug delivery and targeting: Modification, characterization, and in vivo distribution by Rainer H. Müller. Wissenschaftliche Verlagsgesellschaft CRC Press; (1991).
6. Submicron Emulsions in Drug Targeting and Delivery (Drug Targeting and Delivery) by Simon Benita (Editor) Taylor & Francis; (October 1, 1999)
7. Multiparticulate Oral Drug Delivery. Isaac Ghebre-Sellassie (Editor) Marcel Dekker; 1st edition (June 15, 1994)
8. Trends and Future Perspectives in Peptide and Protein Drug Delivery (Drug Targeting and Delivery) by Mitsuru Hashida, Yutaka Mizushima (Editor), V. Lee (Editor). Taylor & Francis; (February 1, 1995)
9. Peptide & Protein Drug Delivery by Frokjaer Munksgaard International Publishers; 1st edition (October 1998).
10. Peptide and Protein Drug Delivery by Vincent H.L. Lee (Editor) Marcel Dekker; (November 19, 1990).
11. Protein Formulation and Delivery Series Volume: 99 Edited By: Eugene McNally 1999.
12. Drug Delivery to the Lung by Hans Bisgaard (Editor), Chris O'Callaghan (Editor), Gerald C. Smaldone (Editor) Marcel Dekker; 1st edition (January 15, 2002)

13. Trends and Future Perspectives in Peptide and Protein Drug Delivery (Drug Targeting and Delivery) by Mitsuru Hashida, Yutaka Mizushima (Editor), V. Lee (Editor)
14. Liposomes in Biomedical Applications (Drug Targeting and Delivery) by Pang N. Shek (Editor) Taylor & Francis; (September 1, 1995).
15. Drug Targeting Technology. Physical-Chemical-Biological Methods Series Volume: 115 Edited By: Hans Schreier, Marcel Dekker 2001
16. Handbook of Biodegradable Polymers (Drug Targeting and Delivery) by A. J. Domb (Editor), Joseph Kost (Editor), David M. Wiseman (Editor) 2001
17. Biorelated Polymers and Gels: Controlled Release and Applications in Biomedical Engineering by Teruo Okano (Author) Academic Press; 1st edition (May 15, 1998)
18. Smart Polymers for Bioseparation & Bioprocessing by Bo Mattiasson (Editor), Igor Galaev (Editor), Kenneth Katzner. Harwood Academic Pub; 1st edition (June 15, 2002)
19. Coronary Artery Stenting ed. S Goldberg, Cooper Synergy Blackwell, 2001

Core Subject : Models for DDS evaluation

cc	Content	Hrs
1	Pharmacodynamic models for evaluation of DDS containing drugs of various categories eg. Cardiovascular agents; Antidiabetic; Antiinflammatory; Antiepileptic; Anticancer; Hepatoprotectives; Analgesics; Antistress; Antiasthmatic and Antitussives etc.	12
2	In vitro cell culture techniques for evaluation of drug permeation from DDS, including isolation maintenance of cell lines, culturing monolayers, evaluation of drug transport.	6
3	In vitro / ex vivo models for evaluation of Drug absorption	3
4	In vitro cytotoxicity evaluation using cell cultures and techniques such as MTT assay, Dye uptake etc.	3
5	Toxicity testing : In vitro : In vitro toxicity testing and its application to safety evaluation, General perspectives, in vitro toxicity trends and issue, Ocular and cutaneous irritation, Validation of In vitro toxicity tests. Acute, sub acute and chronic toxicity testing – Biochemical basis of toxicity, Design of toxicological studies, Quality assurance in toxicology studies, Toxicity by routes – Parental, oral, percutaneous and inhalation, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity. Regulatory status – Ethical, moral and professional issues.	6
Total		30

Books

1. Bioassay Techniques for drug Development, Atta Ur Rahman, M. Iqbal Choudhary, William J. Thomsen
2. In vitro Methods in Pharmaceutical Research, Edited by J.V. Castell, M.J. Gomer, Lechon, Academic Press
3. In vitro Toxicity Testing by John M. Fraizer
4. General and Applied Toxicology by Bryan Ballantyne, T. Marrs & P. Turner.

Elective : Instrumental Techniques for DDS Characterization

No	Content	Hrs
1	Principle, instrumentation, sample preparation, precautions, sample analysis, data interpretation for the following techniques with reference to DDS:	5
	Thermal analytical methods including DSC, TGA;	3
	XRD; FTIR;	5
	SEM; TEM; AFM;	2
	Circular Dichroism;	3
	SANS and SAXS;	7
	Particle size analysis by PCS; SDS – PAGE analysis;	5
	LC – MS; NMR; Gamma scintigraphy	
	Total	30

Books

1. Principles of Instrumental analysis 3rd edition, by Skoog, D.A. 1985
2. Fourier Transform Infrared Spectrometry by Peter Griffiths, Wiley & sons. Pubs. Vol. 83, 1986
3. Mass Spectrometry Advances by ER Schmid, 1983
4. Electron Microscopy – The principles and practice of electron microscopy by Ian Watt, Cambridge University, 1985
5. Surface Analysis with Scanning Transmission Microscopy and Atomic Force Microscopy by S.N. Magonov, VCH Press, 1996
6. The Use of the Scanning Electron Microscope Heale / Pergamon Press, 1972
7. Chemical Applications of Transmission Electron Microscopy by J. Fryer, Academic Press, 1979.
8. Elements of X-ray diffraction, B.D.Cullity, Wesley Publisher, 1956
9. The interpretation of X-ray diffraction photographs by Henry, London Macmillan and Co., 1961
10. Differential thermal analysis by R.C. Mackeuzie, New York, Academic Press, 1972
11. Thermal Characterization Techniques by Slade and Jenkins, New York, Marcel Dekker, 1970
12. Handbook of Biomaterials Evaluation: Scientific, Technical, and Clinical Testing of Implant Materials by Andreas Von Recum, Andreas Von Recum Hemisphere Pub; 2nd edition (December 1998)
13. Scattering in Polymeric and Colloidal Systems by Wyn Brown (Editor), Kell Mortensen (Editor) Taylor & Francis; (August 1, 2000)
14. Characterization of Nanophase Materials by Zhong Lin Wang (Editor) Vch Verlagsgesellschaft MbH; (January 12, 2000)
15. Nanoparticles and Nanostructured Films : Preparation, Characterization and Applications by Janos H. Fendler (Editor) John Wiley & Sons; (August 10, 1998)
16. Particle Size Analysis in Pharmaceuticals and Other Industries: Theory and Practice (Ellis Horwood Series in Pharmaceutical Technology) by Clive, Ph.D. Washington Ellis Horwood Ltd; (February 1993)
17. Surfaces, Interfaces, and Colloids: Principles and Applications, 2nd Edition by Drew Myers (Author), John Wiley & Sons; 2 edition (May 10, 1999)
18. Microcharacterization of Proteins by Roland Kellner (Author), Friedrich Loutspeich (Author), Helmut E. Meyer (Author) John Wiley & Sons; 2nd edition (May 25, 1999)
19. Applied Infrared Spectroscopy: Fundamentals, Techniques, and Analytical Problem-Solving by A. Lee Smith (Author) John Wiley & Sons; (June 25, 1979)
20. Microstructural Characterization of Materials by David G. Brandon (Author), Wayne D. Kaplan (Author) John Wiley & Sons; (July 2, 1999)

Elective: Validation and Regulatory Compliance

No	Content	Hrs
1	Validation: Definition and concepts of prospective concurrent, retrospective and revalidation	3
2	Process and Product validation and Quality audits for illustrative DDS including Analytical Method Validation.	8
3	Documentation – Importance and Generation with reference to regulatory requirements FDA approval,	7
4	NDA, ANDA, IIG, Orange book, International Regulatory Authorities	4
5	Regulatory requirements for setting up a DDS facility	3
6	cGMP and quality assurance	5
	Total	30

Books

1. Validation of Pharmaceutical Processes, Sterile Products Second Edition, Revised and Expanded, Edited By: F. J. Carleton, J. P. Agalloco, Marcel Dekker Inc. 05 Nov 1998
2. Pharmaceutical Process Validation: An International Edition (Drugs and the Pharmaceutical Sciences, Vol 129) by Ira R. Berry (Editor), Alfred Wachter (Editor), Robert Nash (Editor), James Swarbrick., 2000.
3. New drug approval process. Vol. 56, edited by Richard Guarino, Marcel Dekker, 1993.
4. Pharmaceutical Process Validation. Vol. 23, Edited by BT Loftus, RA Nash, Marcel Dekker. 1993.
5. Good Laboratory Practice regulations – by Hirsch, A.F. – New York : Marcel Dekker Inc., 1989
6. Good Laboratory practice regulations / by Sandy Weinberg – New York. Marcel Dekker Inc., 1995.
7. Good manufacturing practices for pharmaceuticals – 3rd ed – New York. Marcel Dekker Inc., 1992.
8. Good manufacturing practices for pharmaceuticals : a plan for total quality control / by S.H. Willig – 2nd ed. New York : Marcel Dekker Inc. 1982
9. Good Laboratory practice : the why and the how by P. Jurg Seilor – Berlin : Springer, 2001.