DEPARTMENT OF PHARMACY

Faculty of Science

COMILLA UNIVERSITY

Kotbari, Cumilla-3506, Bangladesh

SYLLABUS
of
Master of Pharmacy (M. Pharm)

Sessions: 2018-2019, 2019-2020, 2020-2021

Preface:

Comilla University introduces a one (01) year Master of Pharmacy (M. Pharm) degree program under the Faculty of Science, Department of Pharmacy to produce competent pharmacists. Pharmacy is practiced in a wide range of settings including the pharmaceutical industry, drug research and development, pharmaceutical regulations, community pharmacies, hospitals and many other health sectors.

Qualification for Admission:

Students passing B. Pharm. degree from the university may be admitted to the program of Master of Pharmacy in this university on such terms and conditions as may be determined by the university from time to time.

Course Curriculum:

The courses of study for the degree of Master of Pharmacy under the Department of Pharmacy will extend over one academic year. The academic session of the program will be held in two (02) six monthly semesters. Examination will be held at the end of each semester under the following heads:

Syllabus Structure

Thesis Group

Examination	Semester	Credits	Total Credits
M. Pharm.	First	15	36
	Second	21	

Non Thesis Group

Examination	Semester	Credits	Total Credits
M. Pharm.	First	17	36
	Second	19	

Duration of Theory Examination

For 3 credit courses - 3 hours

Total Credit Hours Requirement and Duration of the Program:

To obtain Master of Pharmacy (M. Pharm.) degree, students will have to complete 36 credit hours with a minimum CGPA of 2.25. The program having 2 semesters extends over a period of **1 (one)** academic year and shall be completed by a student in not more than **2 (two)** academic years.

Duration of the Academic Program:

The academic year is divided into two semesters to be called as 1st semester and 2nd semester. An academic semester comprised of six months is distributed as follows:

i.	Class Teaching (actual class)	= 13 weeks
ii.	Preparation time for semester final examination	= 2 weeks
iii.	Semester final examination	= 3 weeks
	Total weeks	**= 18**

Final examination may be scheduled during holidays. Within one week after the semester final examination classes of the next semester will resume.

a) Definition of credit hour:

- Three credit hour refers to three lecture hours per-week for thirteen weeks.

b) Gap between examinations of two courses

- Full unit (3 credits) - not more than 3 days' gap between two courses. (if weekly or national holidays do not make it longer)

Medium of Instruction:
The medium of instruction of the program shall be English.

Class Hours (50 minutes each)
Theoretical and Practical courses shall be so designed as to be completed of the following class hours:

a. Theoretical courses of 3 in 39 class hours
b. Practical courses of 1 credits in 13×2 class hours and 2 credits in 13×4 class hours

Degree Requirements:

a. For a student requires to:

i. Earn required number of total credit points successfully;
i. Earn a minimum CGPA of 2.25; and
ii. Complete the program within two academic years from her/his 1st admission to the program.

b. Award of (Pass) Degree:

i. A student who fails to secure a minimum CGPA of 2.25 after completing 2nd semester final examination but succeeds in securing a CGPA between 2.00 and 2.25 will be eligible for a Pass Degree.

Examination Entry Requirements:
A student will be allowed to take part in semester final examination if s/he fulfills the following conditions:

a. If the student has registered for the concerned semester in due time.
b. If s/he has the required percentage of attendance in each course lecture.
c. If the student has paid all dues (registration fees/tuition fees/other charges) applicable to university administration/residential hall administration etc.)
d. If the student has not been instructed by the Disciplinary Board/Examination Disciplinary Committee to refrain from taking part in the examination.

Improvement of Grade:
Only the removal of 'F' (Fail) in any course shall be allowed. Removal of 'F' in any course is permitted sitting in the final examination only for two (2) times in subsequent two semesters excluding the regular examination.

Drop Out:

a. If a student re-admitted twice in any semester fails to earn minimum required credits for promotion shall be dropped out from the programme.
b. If a student fails to earn required total credit points within two academic years since admissions, s/he will be dropped-out from the programme and will no more be allowed to continue his/her studentship with other programmes.

Re-admission:

a. A student failing to earn the requisite credit points for promotion from one semester to the next may seek re-admission with the following batch.

b. For re-admission a student shall have to apply within one month after the announcement of the result of the concerned semester.

Credit Transfer:
No Credit transfer from any other programmes /University /Institutions to the Comilla University is allowed.

Evaluation System:

A. Theoretical courses

Each theoretical course offered should be composed of either 50 (each 50 marks course consisting of 2 credit point) or 100 marks (each 100 marks course consisting of 3 credit point). The proportion of the total marks of a particular course shall be distributed as follows:

Continuous Assessment /Before-Final Assessment	40%
Semester-Final Examination	60%
Total	**=**

100%

Continuous Assessment: Marks allocated for before-final assessment shall be distributed as follows:

i. ***Internal Evolution:***

a) Mid-Semester examination (at least two mid-semester exams.)	20%
b) Class test and/or quiz and/or in-course and/or sudden test and/or tutorial and/or assignment and/or term paper preparation & presentation/ case study and/or practical and/or field work*	15%
Class Attendance	5%
Total =	**40%**

ii ***Class Attendance:*** The marks allocated for class attendance shall be given as following proportions:

Attendance	**Marks**
90% and above	100%
85% to less than 90%	90%
80% to less than 85%	80%
75% to less than 80%	70%
70% to less than 75%	60%
65% to less than 70%	50%
60% to less than 65%	40%
Less than 60%	0%

*Concerned department and/or course teacher will decide the allocation of this mark in different activities.

Class-Attendance Requirements to Appear in the Semester Final Examination:

i. If class attendance of any student at any course is below 60%, but in the range of 40% to 59%, s/he will be allowed to attend the examination only with the recommendation of the course teacher and approval of the chairman of the department. In such cases the student will have to pay a fine as fixed by the authority/department.

ii. A student with class attendance of less than 40% in any course will be debarred from appearing in the Final Examination.

Letter Grade and Grade point: Total marks obtained in each course, oral (viva-voce) examination and practical courses shall be converted into LG (Letter Grade) and GP (Grade point) as follows:

Numerical Grade	**Letter Grade**		**Grade point**	**Interpretation**
80% and above	A+	(A Plus)	4.00	Outstanding
75% to less than 80%	A	(A regular)	3.75	Excellent
70% to less than 75%	A-	(A minus)	3.50	Very Good
65% to less than 70%	B+	(B Plus)	3.25	Good
60% to less than 65%	B	(B regular)	3.00	Satisfactory
55% to less than 60%	B-	(B minus)	2.75	Below Satisfactory
50% to less than 55%	C+	(C Plus)	2.50	Average
45% to less than 50%	C	(C regular)	2.25	Pass
40% to less than 45%	D	.....	2.00	Poor
Less than 40%	F	.....	0.00	Fail

* In the Transcript/Grade sheet, only the Letter Grade and the Corresponding Grade points, and final CGPA (in the 10th Semester), not the numerical marks, will be shown.

B. Practical Courses

Credit specification:

Different credits will be assigned to laboratory courses as mentioned in the syllabus of the department on the basis of importance. Two laboratory hours per week for the duration of 13

weeks will be considered as one (1) credit and four laboratory hours per week for the duration of 13 weeks will be considered as two (2) credits.

Laboratory Examination:

For lab courses students will evaluated in two phases. The marks distribution will be as follows:

Continuous Assessment: 40%

Lab Attendance:	10%
Lab Performance:	20%
Lab Report Writing:	10%

Final Assessment: 60%

Evaluation on Experiments:	50%
Viva-voce:	10%

Detail distribution of marks for the evaluation on experiment will be decided by the examination committee and the course teachers.

Courses and Credits
Thesis Group

M. Pharm Year I: Semester-1		
Course Code	**Course Title**	**Credit/s**
PHARM 6101	Advanced Pharmaceutical Technology	3
PHARM 6102	Advanced Pharmacology and Toxicology	3
PHARM 6103	Advanced Clinical Pharmacy	3
PHARM 6104	Advanced Medicinal Chemistry and Drug Targeting	3
PHARM 6105	Research Methodology	3
PHARM 6106	Thesis Work (To be continued in semester 2)	
Total Credits		**15**
M. Pharm Year I: Semester-2		
PHARM 6106	Thesis Work (Continuation from Semester I)	6
PHARM 6201	Advanced Pharmaceutical Analysis	3
PHARM 6202	Advanced Biopharmaceutics and Pharmacokinetics	3
PHARM 6203	Genetic Engineering and Biotechnology	3
PHARM 6204	Advanced Molecular Biology	3
PHARM 6205	Theses Defense and Viva voce	3
Total Credits		**21**

Non Thesis Group

M. Pharm Year I: Semester-1		
Course Code	**Course Title**	**Credit/s**
PHARM 6101	Advanced Pharmaceutical Technology	3
PHARM 6102	Advanced Pharmacology and Toxicology	3
PHARM 6103	Advanced Clinical Pharmacy	3
PHARM 6104	Advanced Medicinal Chemistry and Drug Targeting	3
PHARM 6105	Research Methodology	3
PHARM 6107	Advanced Pharmaceutical Technology Lab	1
PHARM 6108	Advanced Pharmacology and Toxicology Lab	1
Total Credits		**17**
M. Pharm Year I: Semester-2		
PHARM 6201	Advanced Pharmaceutical Analysis	3
PHARM 6202	Advanced Biopharmaceutics and Pharmacokinetics	3
PHARM 6203	Genetic Engineering and Biotechnology	3
PHARM 6204	Advanced Molecular Biology	3
PHARM 6206	Advanced Biopharmaceutics and Pharmacokinetics Lab	1
PHARM 6207	Project Work	3
PHARM 6208	Viva Voce	3
Total Credits		**19**

M. Pharm 1st Year 1st Semester

Course Title: Advanced Pharmaceutical Technology

Course Code: PHARM 6101

Credits: 3

1. Advanced drug Delivery Systems: Transdermal drug delivery system, mucosal drug delivery system, nasal drug delivery system, liposomes and nanoparticles drug delivery system, Drug delivery to the lungs, biodegradable drug delivery system.

2. ICH guidelines: Q 1- Q12

3. Validation Techniques for Pharmaceutical Industries: Definitions, Scope of vadiation, Hierarchy of validation. Validation protocol, Prospective validation, Retrospective Validation, Concurrent Validation, Revalidation, Validation in pharmaceutical development, Benefits of validation, Process validation: Validation of solid products & sterile products, Facilities, Equipment and Services validation. Raw Materials Validation, Cleaning validation, Analytical methods validation, Packaging components validation. Computer systems Validation

4.Pilot Plant Scale-Up Techniques: Primary function of the pharmaceutical pilot plant, factors to be considered during development, reporting responsibilities, personnel requirements, space requirements, review of the formula, raw materials, relevant processing

equipments, production rates, process evaluation, master manufacturing procedures, GMP considerations, pilot plant design for tablet development.

5. Optimization techniques in pharmaceutical formulation and processing:

Application of optimization techniques in pharmaceutical formulation, Optimization parameters, Statistical design.

6. Materials of pharmaceutical plant construction:

Recommended books:

1. Remington's Pharmaceutical Sciences
2. Dispensing of Pharmaceutical Students – Cooper and Gunn
3. Dispensing of Medication
4. Bentley's Textbook of Pharmaceutics
5. An Introduction to Pharmaceutical Formulations – Fishburn
6. Pharmaceutical Dosage Forms – Ansel
7. Pharmaceutics and Pharmacy Practice – Banker and Chalmers
8. The Art, Science and Technology of Pharmaceutical Compounding – Loyd V. Allen Jr.
9. Theory and practice of Industrial Pharmacy – Lachmann
10. American Pharmacy- Sprowl
11. Pharmaceutics – Aulton
12. Trgeted and controlled Drug Delivery, Novel.

M. Pharm 1st Year 1st Semester

Course Title: Advanced Pharmacology and Toxicology

Course Code: PHARM 6102

Credits: 3

1. Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors. Advances in Receptor Pharmacology (Adrenergic, Cholinergic, 5-HT, GABAergic, Histaminic), Ion Channels, signal transduction and second messenger.

2. The Mechanism of Toxin Action: General mechanisms of toxin-induced cell damage and death – hepatotoxicity and nephrotoxicity, Mutagenesis and carcinogenecity – Biochemical mechanisms of mutagenesis, Carcinogenesis–genotoxic and epigenetic carcinogens, Teratogenesis and drug-induced foetal damage, Allergic reactions to drugs.

3. Cancer Biology and Therapy: Introduction to biology of cancer, modes of treatment: radiotherapy,
chemotherapy, surgery, biological therapy including immunology and gene therapy.

4. Neuropharmacology: a) Pathophysiology of CNS degenerations functional ares of age related senile illnes memory. b) Diseases and treatment of Neurodegenerative disorders - Alzheimer's disease, Parkinson's
disease, Huntington's disease, Neurodegenerative prion disease. eplepsi schizophrenia.

5. Target Organ Toxicity: Blood and Cardiovascular Toxicity, Immuno Toxicity, Neurotoxicity, Hepatic and renal toxicity, reproductive toxicity, skin toxicity, endocrine toxicity, respiratory toxicity, ocular toxicity etc.

6. Human Health Risk Assessment: Dose-response Assessment; analysis of dose and response, extraporation lower doses; linear Vs non-linear approaches

References of Books:

1. The Pharmacological Basis of Therapeutics – by Goodman and Gilman.
2. Pharmacology – by H.P. Rang et al.
3. Pharmacology – by Lippincott et al.
4. Pharmacology – by Kalant et al.
5. Basic and Clinical Pharmacology – by Bertram G. Katzung.
6. Pharmacology and Therapeutics – by R.S. Satoskar et al.
7. Medical Pharmacology – by Goth.
8. Essentials of Medical Pharmacology – by K.D. Tripatti.

* Other Books will be indicated by respective teachers

M. Pharm 1st Year 1st Semester

Course Title: Advanced Clinical Pharmacy

Course Code: PHARM 6103

Credits: 3

1. GI disorders: Aetiology, pathophysiology, clinical manifestations, principles of management and treatment of - GERD, ulcerative colitis, Crohn's disease and pseudomembranous colitis, ORT, super ORS, relevant case studies.

2. Neurological disorders: Aetiology, pathophysiology, clinical manifestations and clinical management of a) Alzheimer's disease, b) Parkinson's disease, c) Cerebrovascular disease and relevant case studies.

3. Cardiovascular disorders: Aetiology, pathophysiology, clinical manifestations and clinical management of a) Cardiac arrhythmia, b) Myocardial infarction, c) Thrombosis and relevant case studies.

4. Skin disorders: (a) Pressure sores and leg ulcers: Pathophysiology, aetiology, clinical signs and symptoms, investigations and treatment. **(b) Drug induced skin disorders:** diagnosis and treatment, relevant case studies.

5. Rheumatoid disorders: (a) Rheumatoid arthritis and osteoarthritis: Epidemiology, aetiology, pathophysiology, clinical manifestations, investigations and treatment **(b) Gout and hyperuricemia:** Epidemiology, aetiology, pathophysiology, clinical manifestations, investigations and treatment, relevant case studies.

6. Malignant disorders:

Aetiology, pathophysiology, clinical manifestations, principles of management and treatment of major cancers including – colon, lung, ovarian, breast, prostate cancers and leukemia, relevant case studies.

7. Racial, gender and ethnic differences in drug response: Origins of genetic differences among peoples, genetic variation within and between populations, the uses of racial categorization of medicine, interplay of genetic, environmental and cultural factors,

genetic polymorphisms in drug metabolism, drug targets and disease pathways, racial and ethnic variation in polymorphisms in drug metabolism, clinical relevance of genetic polymorphisms, examples of drugs showing varying effects among racial and ethnic groups.

8. Patient counseling and interviewing techniques: What, who and when to counsel, format of counseling provided, counseling area, documentation of counseling, benefits and outcomes of counseling, counseling on non-prescription and prescription drugs, medication counseling tips, patients who should always be counseled and those who should be counseled at certain intervals, roles of pharmacists in reducing medication errors and in improving patient compliance and patient monitoring by effective counseling.

9. Drug information services/resources: Needs for drug information, drug information resources and literature: primary, secondary and tertiary, information retrieval systems, example of online resources for drug related information.

M. Pharm 1st Year 1st Semester

Course Title: Advanced Medicinal Chemistry and Drug Targeting

Course Code: PHARM 6104

Credits: 3

1. **Drug discovery and development:** Drug discovery & development - the post, present, & future, Choosing a disease, and choosing a drug target, Identifying a bioassay, Finding a lead compound, Isolation, purification, structure determination and SAR studies, Optimization of 13 the lead compound - Tailoring the lead compound for improved (specific) drug-target interactions, Identification of pharmacophore and its pattern., Toxicity testing, Clinical trials

a. Quantitative structure - activity relationships (QSAR), and its role in drug design.

b. Drug Discovery by Combinatorial Chemistry and Molecular Diversity: An overview of therapeutic targets for drug discovery, Combinatorial chemistry in drug development, Methods for creating molecular diversity, Principles of combinatorial chemistry, Synthetic strategies for combinatorial chemistry

2. Drug design to improve Pharmacokinetic properties: Pharmacokinetic issues in drug design, Drug design -making drugs more resistant to hydrolysis and metabolism, Drug design-making drug less resistant to drug metabolism, Drug design- targeting drugs, Drug design- reducing toxicity, Various methods of studying drug-target interactions

3. Computer Assisted Drug Design: An overview of the role of computational chemistry in therapeutic drug design, Computational chemistry in small-molecule drug design

a. Designing drugs without a target 3D structure

b. Computational aspects of small molecule design

c. Application of pharmacophore-based drug design

d. Structure-based drug design- use of X-ray and NMR structures

e. De novo drug design based on target 3D structures

f. Applications of structure-based drug design.

4. Molecular Mechanism of Drug Resistance: Drug resistance with reference to cancer and infectious diseases, measures to overcome drug resistance. Novel molecular target discovery.

5. Biosynthesis: Biosynthetic pathways and actions of steroidal hormones, alkaloids,carbohydrates and nucleotides.

6. Metabolite antagonism: Historical development, sulfonamides and Fildes theory of antimetabolites, active site-directed irreversible enzyme inhibitors, mechanism-based enzyme inhibitors, antifolates, sulfonamides and sulfones, dihydrofolate reductance inhibitors, synergism of sulfonamides and dihydrofolate reductance inhibitors, amino acid antagonists, vitamin antaginists, pyrimidine and purine antimetabolites.

Books Recommended:

1. An Introduction to Medicinal chemistry, 2nd.ed. 2001, G.L.Patrick, Oxford University press.
2. Wilson and Gisvolt's Text Book of Organic, Medicinal and Pharmaceutical Chemistry, 10th ed. Lippincott-Raven, 1998
3. Advanced Practical Organic Chemistry, 2nd. ed., by J. Leonard et al.Academic press.
4. Advanced Organic Chemistry, Bernard Miller, Prentice Hall. 1995
5. Advanced Organic Chemistry, Jerry march, Wiley Interscience.
6. Mechanism and theory of Organic Chemistry, Lowry and Richardson, Harper.
7. Physicochemical Principles of Pharmacy, 3rd ed. 1998, A.T. Florence and A.D. Palgrave.

* Other Books will be indicated by respective teachers

M. Pharm 1st Year 1st Semester

Course Title: Research Methodology

Course Code: PHARM 6105

Credits: 3

1. **Research concept methodology and design of research:**

   The basic concepts of conducting research; about the working methods to execute the research, Study and review literature; develop any hypothesis regarding the research; how to conduct a research

2. **Research trends in different pharmaceutical areas:**

   Natural product development, Product development, Purification technology, Analytical method development, Waste management, Reverse engineering technology, Life style products, Bioequivalence study, Veterinary sectors, Food and cosmetics, Biotech products.

3. **Documentation:**

   Comprehend about the process, importance; the techniques of documentation for conducting a research work.

4. **Data collection, preparation and analysis:**

   Ways and importance of data collection and management, various methods for analysis, ANOVA and multiple range test, analysis of frequencies, nonparametric test, Descriptive statistics- Probability and normal distribution, statistical inference and Student's t-test

5. **Report writing/manuscript preparation and publication**

6. Ethical guidelines in clinical research:

The rules; regulations of conduction a clinical research work.

Recommended Books:
D. R. Glasanapp & J. P. Poggio, Essentials of Statistical Analysis for the Behavioral Sciences. 1985. Charles E.Merrill Publishing Company, London.
J. E. Freund and G. A. Simon G A Modern elementary statistics 8th edn, Prentice-Hall, 1992
Beth Dawson and Robert Trapp, Basic & Clinical Biostatistics, 4th Edition, 2004, McGraw-Hill Medical
Kumar, Ranjit, Research Methodology-A Step-by-Step Guide for Beginners, 3rd.ed., 2010, Sage Publications Ltd
Dawson, Catherine, Practical Research Methods, 2002, New Delhi, UBS Publishers'Distributors 16
Larry B. Christensen, R. Burke Johnson and Lisa A. Turner, Research Methods, Design, and Analysis, 11th Edition, 2010, Allyn and Bacon

M. Pharm 1st Year 1st Semester

Course Title: Thesis Work

Course Code: PHARM 6106

Credits: 6

Thesis work will be selected through discussion between the assign supervisors and students. The supervisors will supervise the research activities and report submission.

Evaluation of the course will be in two steps such as:

A. Report Examination: 80%

According to the decision of the academic committee each teacher will supervise students. At the end of the semester, each student will submit 4 copies of project reports (3 reports for the exam committee and 1 copy for the department). The examination committee will send the reports to the external and internal examiner for evaluation (80%). The external and internal examiner will be selected by the exam committee itself. If there is a 20% marks difference between the external and internal examiner, the reports will be evaluated by the third examiner.

B. Oral Assesment /Project Defence (20%) ঃ

Every student must attend the Oral Assessment / Theses Defense ceremony arranged by the exam committee. All the members of the exam committee will evaluate the Oral Assessment / Project Defense. In the absence of any member, the other members of the exam committee can conduct all the examination as per the examination rules of the university

M. Pharm 1st Year 1st Semester

Course Title: Advanced Pharmaceutical Technology Lab

Course Code: PHARM 6107

Credits: 1

1. Preparation of Suppositories.
2. Preparation of Microcapsule and tablets.
3. Particle size analysis.
4. Preparation of topical drugs.
5. Determination of moisture content, melting point, loss upon drying, limit test etc for Pharmaceutical raw materials.

N.B. The course can be designed/modified according to the course teacher.

M. Pharm 1st Year 1st Semester

Course Title: Advanced Pharmacology and Toxicology Lab

Course Code: PHARM 6108

Credits: 1

1. Determination of protein concentration by Lowry and Bradford method.
2. Colorimetric analysis of different drugs from blood sample.
3. Effect of agonists and antagonists on the contraction and relaxation response of the smooth muscles.
4. Effects of drugs on heart.
5. Study of liver and kidney toxicity.
6. Toxic effects of drugs on hematological parameters.
7. Histopathological study of different organs after drug administration.

N.B. The course can be designed/modified according to the course teacher.

M. Pharm 1st Year 2nd Semester

Course Title: Advanced Pharmaceutical Analysis

Course Code: PHARM 6201

Credits: 3

1. Nuclear Magnetic Resonance (NMR) Spectroscopy:

Advanced Techniques and Applications NMR: 1H and 13C NMR, principles, instrumentation, principles of decoupling, gated decoupling, difference spectroscopy, relaxation process, population transfer, selective polarization transfer, INEPT, basic two dimensional sequence, heteronuclear shift correlation, application of DEPT, 1H-1H

COSY, HMBC, HMQC, HOHAHA (TOCSY), NOE's in structure elucidation of organic compounds. NMR in drug screening, reaction monitoring etc. Applications of NMR in medical sciences.

2. **Electron Spin Resonance (ESR) Spectroscopy:**

   Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.

3. **Mass spectroscopy (MS):**

   Theory, instrumentation and ionization methods (FAB, ESI, MALDI, FD, etc.). Application of HRIEMS, MS-MS, GC-MS, LC-MS. Mass spectrometers (MALDI TOF, ES) in structure elucidation of small and macromolecules

4. **High Performance Liquid Chromatography (HPLC):**

   Normal phase, reversed phase, ion exchanges and ion pairing techniques, chiral HPLC. Application of HPLC in analysis of drugs in pharmaceutical preparations and biological fluids.

5. **Separation Technology:**

   a) Gel filtration chromatography: Principle, materials, application. Introduction, instrumentation, detection, modes of separation, efficiency & resolution of gel and capillary electrophoresis, related techniques as temperature gradient gel electrophoresis, SDS-PAGE & its zymography. b) Ion-exchange chromatography: Principle, exchangers, ion exchange column, capacity, techniques and its pharmaceutical application. c) Affinity chromatography: principles, uses, limitation.

M. Pharm 1st Year 2nd Semester

Course Title: Advanced Biopharmaceutics and Pharmacokinetics

Course Code: PHARM 6202

Credits: 3

1. Nonlinear Pharmacokinetics:

Introduction, Characteristics of drugs that follow enzymatic saturation kinetics andexamples, estimationof drug following Michaelis-Menten kinetics, Drug elimination bycapacity limited pharmacokineticprocess, In-vivo estimation of KM and Vmax,Determination of KM and Vmax in patients and by direct methods, Relationship betweenthe area under the plasma concentration versus time curve and the administered dose ordependence of dose on clearance, chronopharmacokinetics and time dependentpharmacokinetics, circadian rhythms and its influence on drug response.

2. Relationship between Pharmacokinetics and Pharmacodynamics:

Introduction, relation of dose to pharmacologic response, relationship between dose andduration of activity, effect of elimination of half-life on duration of activity and clinicalexample, Drug-Receptor theoryrelating pharmacologic effect and dose,Pharmacodynamic models, Maximum effect (Emax) model, pharmacokineticpharmacodynamic models with an effect compartment, pharmacodynamic

models usingan effect compartment, Hysteresis of pharmacologic response, Simulation of in-vitropharmacodynamic effect involving Hysteresis.

3. Application of Pharmacokinetics to Clinical Situations:

Introduction, Individualization of drug dosage regimens, methods for determination ofindividual patient parameters, therapeutic drug monitoring (TDM), pharmacokineticevaluation, design of dosage regimens, conversion from intravenous infusion to oraldosing, determination of dose, effect of changing dose and dosage interval on Cαmax andCαmin and Cαav, determination of frequency of drug administration, determination ofroute of administration, dosing of drugs in infant, pediatric, obese and elderly patient,examples.

4. Physiologic Pharmacokinetic Models, Mean Residence Time, and StatisticalMoment Theory:

Introduction, physiologic pharmacokinetic models, physiologic pharmacokinetic modelswith binding, Application and limitations of physiologic pharmacokinetic models, statisticalmoment theory, introduction to mean residence time, Mean residence time for multicompartment model with elimination from the central compartment, Mean Absorption Time(MAT) and Mean Dissolution Time (MDT), selection of pharmacokinetic models.

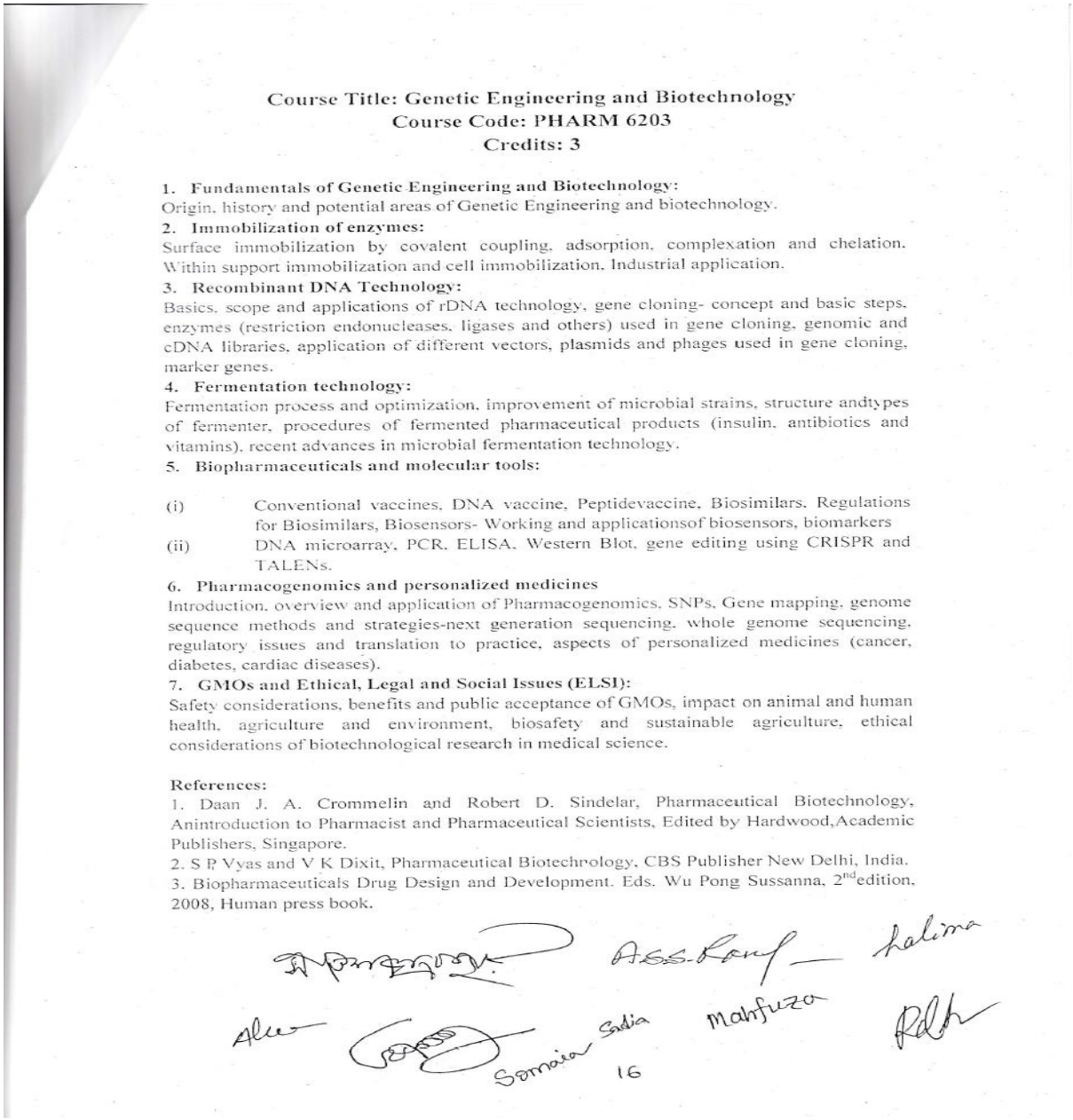
5. Drug Dosing in Special Populations – Renal and Hepatic Disease, Dialysis, CardiacDisease, Obesity, Diabetic Patient and Drug Interactions:

Introduction, renal disease, estimation of drug dosing and pharmacokinetic parametersusing creatinine clearance, Dialysis, drug characteristics that effect dialysis removal,Hemodialysis, methods to measure hemodialysis clearance, Peritoneal dialysis, methodsto measure peritoneal dialysis clearance, Hepatic disease, estimation of drug dosing andpharmacokinetic parameters for liver metabolized drugs, implications of hepatic diseaseon serum drug concentration monitoring and drug effects, drug dosing in heart failure andobese patients, Drug interactions, Plasma protein binding displacement drug interactions,inhibition drug interactions, induction drug interactions.

References:

1. Leon Shargel, Susanna Pong and Andrew B. C. Yu, Applied Biopharmaceutics &Pharmacokinetics by Fifth Revised Edition, The McGraw-Hill Companies, Inc, USA.2005.
2. Milo Gibaldi and Donald Perrier, Pharmacokinetics, Second Edition, Revised andExpanded, Published by Informa Healthcare USA, Inc. 2007.
3. Larry A Bauer, Applied Clinical Pharmacokinetics, Second Edition, Published by TheMcGraw-Hill Companies, USA, Inc. 2008.
4. Sunil S Jambhekar and Philip J Breen, Basic Pharmacokinetics, First Edition,Published by the Pharmaceutical Press, London. 2009.

M. Pharm 1st Year 2nd Semester
Course Title: Genetic Engineering and Biotechnology
Course Code: PHARM 6203
Credits: 3



Course Title: Genetic Engineering and Biotechnology
Course Code: PHARM 6203
Credits: 3

1. **Fundamentals of Genetic Engineering and Biotechnology:**
Origin, history and potential areas of Genetic Engineering and biotechnology.
2. **Immobilization of enzymes:**
Surface immobilization by covalent coupling, adsorption, complexation and chelation. Within support immobilization and cell immobilization. Industrial application.
3. **Recombinant DNA Technology:**
Basics, scope and applications of rDNA technology, gene cloning- concept and basic steps, enzymes (restriction endonucleases, ligases and others) used in gene cloning, genomic and cDNA libraries, application of different vectors, plasmids and phages used in gene cloning, marker genes.
4. **Fermentation technology:**
Fermentation process and optimization, improvement of microbial strains, structure andtypes of fermenter, procedures of fermented pharmaceutical products (insulin, antibiotics and vitamins), recent advances in microbial fermentation technology.
5. **Biopharmaceuticals and molecular tools:**

(i) Conventional vaccines, DNA vaccine, Peptidevaccine, Biosimilars, Regulations for Biosimilars, Biosensors- Working and applicationsof biosensors, biomarkers
(ii) DNA microarray, PCR, ELISA, Western Blot, gene editing using CRISPR and TALENs.

6. **Pharmacogenomics and personalized medicines**
Introduction, overview and application of Pharmacogenomics, SNPs, Gene mapping, genome sequence methods and strategies-next generation sequencing, whole genome sequencing, regulatory issues and translation to practice, aspects of personalized medicines (cancer, diabetes, cardiac diseases).
7. **GMOs and Ethical, Legal and Social Issues (ELSI):**
Safety considerations, benefits and public acceptance of GMOs, impact on animal and human health, agriculture and environment, biosafety and sustainable agriculture, ethical considerations of biotechnological research in medical science.

References:
1. Daan J. A. Crommelin and Robert D. Sindelar, Pharmaceutical Biotechnology, Anintroduction to Pharmacist and Pharmaceutical Scientists, Edited by Hardwood,Academic Publishers, Singapore.
2. S P Vyas and V K Dixit, Pharmaceutical Biotechnology, CBS Publisher New Delhi, India.
3. Biopharmaceuticals Drug Design and Development. Eds. Wu Pong Sussanna, 2nd edition, 2008, Human press book.

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References:

1. Daan J. A. Crommelin and Robert D. Sindelar, Pharmaceutical Biotechnology, Anintroduction to Pharmacist and Pharmaceutical Scientists, Edited by Hardwood,Academic Publishers, Singapore.
2. S P Vyas and V K Dixit, Pharmaceutical Biotechnology, CBS Publisher New Delhi, India.
3. Biopharmaceuticals Drug Design and Development. Eds. Wu Pong Sussanna, 2nd edition, 2008, Human press book.
4. Biopharmaceuticals: Biochemistry and Biotechnology, 2nd edition Gary Walls, Wileypublications.
5. Introduction to Food Science, Rick Parker, Thomson Learning Inc, USA.

6. Food Additives, Second Edition, A. Larry Branen, P. Michael Davidson, Marcel DekkerInc.,USA.
7. Encyclopedia of Food Science and Technology-by Francis, The Computype Media,India.

M. Pharm 1st Year 2nd Semester

Course Title: Advanced Molecular Biology

Course Code: PHARM 6204

Credits: 3

1. Regulation of Gene Expression:

a) Characterization and identification of cis and trans elements, methodology, mechanism of transcription repression by methylation, silencers.

b) Regulation in Prokaryotes- Transcriptional regulation in prokaryotes (inducible and repressible system, positive regulation and negative regulation); Operon concept – lac., trp., and ara. operons.

c) Regulation in Eukaryotes: Regulatory strategies in Eukaryotes, Gene alteration (Gene loss, Gene amplification, Gene rearrangement: the joining of coding sequences) Transcriptional control by hormones, Regulation mediated through transcription factors, Regulation of enhancer activity, Methylation, Regulation of processing, Translational control.

2. Gene Replacement and Transgenic Animals: Cloning, purposes and risks of cloning, stem cells, definition & classification, generation and uses of transgenic & knockout/gene targeting animal models to study genetic diseases.

3. Gene Therapy: Central concept of gene therapy, basic molecular mechanism of gene transfer, prerequisite of human gene therapy, biological basis of gene therapy strategies, vehicles for gene transfer, Antisence oligonucleotides and RNAi, clinical gene therapy studies, gene therapy for hereditary disease, gene therapy for cancer, gene therapy for HIV.

4. Repair Mechanism of DNA: DNA damage, Mechanism of different types of DNA repair system in bacteria and their relation with carcinogenesis.

5. Basic Immunity: Natural and acquired immunity, Innate and adaptive immunity, Effector mechanisms of phagocytes, natural killer (NK) cells, T lymphocytes and B lymphocytes in immune responses; Cytokines and their roles in immune responses.

References:

1. Cellular and Molecular Immunology by Abul K Abbas, Andrew H Lichtman, Jordan S Pober
2. Immunology by Ivan Roitt, Jonathan Brostoff , David Male
3. Molecular Biology by PC Turner, AG Mclennam, AD Bates
4. The Cell: A molecular Approach by Alberts B et al

5. Molecular Cell Biology by Lodish et al
6. Molecular Biology of Cells by Alberst et al
7. Applied therapeutics by young kode kihble et.al.
8. Hand book of Drug Interaction by karalliedde & Hanry
* Other Books will be indicated by respective teachers

M. Pharm 1st Year 2nd Semester

Course Title: Thesis Defense and viva Voce

Course Code: PHARM 6205

Credits: 3

Every student must attend the Oral Assessment / Theses Defense ceremony arranged by the exam committee. All the members of the exam committee will evaluate the Oral Assessment / Theses Defense. In the absence of any member, the other members of the exam committee can conduct all the examination as per the examination rules of the university

M. Pharm 1st Year 2nd Semester

Course Title: Advanced Biopharmaceutics and Pharmacokinetics Lab

Course Code: PHARM 6206

Credits: 1

1. In vitro study of bioavailability of drug: (a) Disintegration and dissolution tests of solid dosage forms.
2. In vivo study of bioavailability of drug: (a) Determination of concentration of aspirin in urine after oral administration (b) Determination of paracetamol in blood after oral administration
3. Evaluation of release pattern of advanced SRDF products.
4. Evaluation of TDDS drugs.
5. Evaluation of aerosol products drugs.

N.B. The course can be designed/modified according to the course teacher.

M. Pharm 1st Year 2nd Semester

Course Title: Project Work

Course Code: PHARM 6207

Credits: 3

Research projects will be selected through discussion between the assign supervisors and students. The supervisors will supervise the research activities and report submission.

Evaluation of the course will be in two steps such as:

A. Report Examination: 80%

According to the decision of the academic committee each teacher will supervise students. At the end of the semester, each student will submit 4 copies of project reports (3 reports for the exam committee and 1 copy for the department). The examination committee will send the reports to the external and internal examiner for evaluation (80%). The external and internal examiner will be selected by the exam committee itself. If there is a 20% marks difference between the external and internal examiner, the reports will be evaluated by the third examiner.

B. Oral Assesment /Project Defence (20%) ঃ

Every student must attend the Oral Assesment / Project Defence ceremony arranged by the exam committee. All the members of the exam committee will evaluate the Oral Assesment / Project Defence. In the absence of any member, the other members of the exam committee can conduct all the examination as per the examination rules of the university.

M. Pharm 1st Year 2nd Semester

Course Title: Viva Voce

Course Code: PHARM 6208

Credits: 3

Every student (Non-thesis) must give a Viva voce at the end of M. Pharm 2nd Semester. Topics of the viva voce will cover from any course of entire M. Pharm program and current affairs of pharmaceuticals.