BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY

बाबासाहेब भीमराव अम्बेडकर विश्वविद्यालय
विद्या–विहार, रायबरेली रोड, लखनऊ–226025

BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY
(A Central University)
Vidya Vihar, Raebreli Road, Lucknow-226025

Letter No.: 1550/D.Ph.Sc./BBAU/20 **Date: 18-11-2020**

Notice

This is to inform to all concerned that the Department of Pharmaceutical Sciences is offering 02 (two) Optional paper under open Elective course in 1st semester. Any one of these can be opted by any student under the Choice Based Credit System being followed by the University. For other details regarding time- schedule please refer the Notice Board of the Department of Pharmaceutical Sciences. **Dr. Sapan Kushwaha**, Assistant Professor Department of Pharmaceutical Sciences is the student advisor, for this paper. The papers are as given below:

Course Code	**MPL-104 T**
Course Title	Cellular Molecular Pharmacology
Type of Paper	Open Elective
Credits	4
Teaching Hours	60

Course Code	**MPH 104 T**
Course Title	Regulatory Affairs
Type of Paper	Open Elective
Credits	4
Teaching Hours	60

Head,
Department of Pharmaceutical Sciences

Copy to:

1. A.R to V.C office for kind information of Hon,ble Vice chancellor, BBAU,LKO
2. Dean Academic Affairs, BBAU Lko
3. All Deans with a request to give it a wide publicity among the students of all Departments under their school
4. Registrar, BBAU, LKO
5. COE, BBAU,LKO
6. Notice Board
7. I/C University website for its uploading on university website

Head,
Department of Pharmaceutical Sciences

DEPARTMENT OF PHARMACEUTICAL SCIENCES

School for Pharmaceutical Sciences (SPS)

M. Pharm Pharmacology
Course folder/Course View

Academic Session 2020-21 **Semester –I**

1. General Course Information: The Department of Pharmaceutical Sciences, School for Biomedical & Pharmaceutical Sciences, runs M. Pharm Programme. This course is to be offered under CBCS to all student under open Elective course. This course aims to acquaint the students about different National and International information system and programmes.

1.1 Course Title: Cellular Molecular Pharmacology
1.2 Course Code: MPL-104T
1.3 Credits: 04
1.4 Teaching hours: 60Hours
1.5 Semester offered: One
1.6 Lecture: 09:30A.M. to10:30 A.M (Monday to Saturday)
1.7 Teachers Name : Dr. Gaurav Kaithwas

Course Objective: The objective of this open elective course under CBCS is

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology.

THEORY

1-Cell biology :-
Structure and functions of cell and its organelles Genome organization, Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation.
Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

2-Cell signaling :-
Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, itogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3-Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4-Pharmacogenomics :-

Gene mapping and cloning of disease gene. Genetic variation and its role in health, pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

5-a. Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry

b- Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach, Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

DEPARTMENT OF PHARMACEUTICAL SCIENCES

School for Pharmaceutical Sciences

M. Pharm Pharmaceutics
Course folder/Course View

Academic Session 2020-21 **Semester –I**

1. General Course Information: The Department of Pharmaceutical Sciences, School for Biomedical & Pharmaceutical Sciences, runs M. Pharm Programme. This course is to be offered under CBCS to all student under open Elective course. This course aims to acquaint the students about different National and International information system and programmes.

1.1 Course Title: **Regulatory Affairs**
1.2 Course Code: MPH-104T
1.3 Credits: 04
1.4 Teaching hours: 60 Hours
1.5 Semester offered: One
1.6 Lecture: 09:30A.M. to10:30 A.M (Monday to Saturday)

Course Objective: The objective of this open elective course under CBCS is:

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials

THEORY

1.

a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records, Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

b. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q1 and Q2 .Basic Regulatory requirements of EU, MHRA, TGA and ROW countries.

3. Non clinical drug development: Global submission of IND, NDA, ANDA, Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD.5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics