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.: 118 **/D.Ph.Sci./BBAU/24** **Date:** 07-08-2024

Notice

This is to inform to all concerned that the Department of Pharmaceutical Sciences is offering 03 (three) 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. Vikas Mishra**, Department of Pharmaceutical Sciences is the student advisor, for these 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

Course Code	**MPA-104 T**
Course Title	Food Analysis
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 H'onable 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

Semester –I

1. General Course Information: The Department of Pharmaceutical Sciences, School of Pharmaceutical Science, 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

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 Science

M. Pharm Pharmaceutics
Course folder/Course View

Semester –I

1. General Course Information: The Department of Pharmaceutical Sciences, School of Pharmaceutical Science, 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

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

DEPARTMENT OF PHARMACEUTICAL SCIENCES
School for Pharmaceutical Science

M. Pharm Pharmaceutical Analysis
Course folder/Course View

Semester –I

1. General Course Information: The Department of Pharmaceutical Sciences, School of Pharmaceutical Science, 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	:	FOOD ANALYSIS (MPA 104T)
1.2 Course Code	:	(MPA 104T)
1.3 Credits	:	04

Course Objective: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations andlegislations

THEORY

1. Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2 Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3 Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, theiroccurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4 General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

5 Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of 9 food products with special emphasis on BIS, Agmark, FDA and US-FDA

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones &Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.