



स्वामी रामानंद तीर्थ मराठवाडा विद्यापीठ

नांदेड— ४३१६०६ (महाराष्ट्र)

SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY

NANDED-431606, MAHARASHTRA STATE, INDIA.

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ACADEMIC (1-BOARD OF STUDIES) SECTION

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औषधनिर्माणशास्त्रे विद्याशाखेंतर्गत संलग्नित शिवलिंगेश्वर कॉलेज ऑफ फार्मसी, अलमला, ता. औसा, जि. लातूर या महाविद्यालयातील Pharm.D. (Doctor of Pharmacy) विषयाचा अभ्यासक्रम शैक्षणिक वर्ष २०१६-१७ पासून लागू करण्याबाबत.

प रि प त्र क

या परिपत्रकान्वये सर्व संबंधितांना कळविण्यात येते की, दिनांक ०३ मे २०१७ रोजी संपन्न झालेल्या ३८व्या मा. विद्या परिषद बैठकीतील विषय क्र.१२५/३८-२०१७ च्या ठरावानुसार औषधनिर्माणशास्त्रे विद्याशाखेंतर्गत शिवलिंगेश्वर कॉलेज ऑफ फार्मसी, अलमला, ता. औसा, जि. लातूर या संलग्नित महाविद्यालयात खालील अभ्यासक्रम शैक्षणिक वर्ष २०१६-१७ पासून लागू करण्यात येत आहे.

1. Pharm.D. (Doctor of Pharmacy)

सदरील परिपत्रक व अभ्यासक्रम प्रस्तुत विद्यापीठाच्या www.srtmun.ac.in या संकेतस्थळावर उपलब्ध आहेत. तरी सदरील बाब ही सर्व संबंधितांच्या निदर्शनास आणून द्यावी.

‘ज्ञानतीर्थ’ परिसर,

विष्णुपुरी, नांदेड — ४३१ ६०६.

जा.क्र.: शैक्षणिक-०१/परिपत्रक/औषधनिर्माणशास्त्रे/

२०१६-१७/२५

दिनांक : ०५.०६.२०१७.



स्वा/-

उपकुलसचिव

शैक्षणिक (१-अभ्यासमंडळ) विभाग

प्रत : माहिती व पुढील कार्यवाहीस्तव :

- १) मा. कुलसचिव यांचे कार्यालय, प्रस्तुत विद्यापीठ.
- २) मा. संचालक, परीक्षा व मूल्यमापन मंडळ, प्रस्तुत विद्यापीठ.
- ३) प्राचार्य, शिवलिंगेश्वर कॉलेज ऑफ फार्मसी, अलमला, ता. औसा, जि. लातूर — ४१३५२०.
- ४) उपकुलसचिव, पदव्युत्तर विभाग, प्रस्तुत विद्यापीठ.
- ५) साहाय्यक कुलसचिव, पात्रता विभाग, प्रस्तुत विद्यापीठ.
- ६) सिस्टम एक्सपर्ट, यू.जी.सी. कक्ष, प्रस्तुत विद्यापीठ.



भारत का राजपत्र The Gazette of India

साप्ताहिक/WEEKLY

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4

[PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by
Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

संदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

“अरब बांगलादेश बैंक लिमिटेड” शब्दों के स्थान पर “एबी बैंक लिमिटेड” शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology :

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Phrmacoeconomics:

Definition, history, needs of pharmaco-economic evaluations

Role in formulary management decisions

Pharmaco-economic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmaco-economics

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

- 1. Introduction to Clinical pharmacokinetics.**
- 2. Design of dosage regimens:**

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
- 3. Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
- 4. Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
- 5. Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
- 6. Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
- 7. Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B
(See regulation 9)
CONDITIONS TO BE FULFILLED BY THE
ACADEMIC TRAINING INSTITUTION

- 1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- 2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

- a) Tertiary care hospitals are desirable
- b) Medicine[compulsory], and any three specialization of the following
 1. Surgery
 2. Pediatrics
 3. Gynecology and obstetrics
 4. Psychiatry
 5. Skin and VD
 6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.