5th SEMESTER
PHARMACY
(PHARMACEUTICAL SALES MANAGEMENT)
SKILL ENHANCEMENT COURSE (SEC)

PSM520S: PSM-II - PHARMACOLOGY AND PHARMACEUTICAL REGULATORY AFFAIRS

CREDITS: THEORY: 2, PRACTICAL: 2
MAX MARKS: THEORY: 30, PRACTICAL: 30
MIN MARKS: THEORY: 12, PRACTICAL: 12

THEORY (2 CREDITS)

UNIT 1

1.1 General Pharmacology (3 hours)

Introduction and scope of pharmacology, various routes of drug administration – advantages and disadvantages, general overview of absorption, distribution, metabolism and elimination (ADME).

Introduction, Definition, classification, pharmacological action, dose, indications and contraindications of the following (two examples from each class):

1.2 Drugs Acting on Nervous System (4 hours)

Central Nervous System – General anesthetics, Anticonvulsant drugs, Antidepressant drugs, Opioid analgesics, Non-Steroidal Anti-Inflammatory drugs (NSAIDs).

1.3 Drugs Acting on the Cardiovascular System (3 hours)

Antihypertensive drugs, Antianginal drugs, Antiarrhythmic drugs

1.4 Drugs acting on the respiratory system (2 hours)

Bronchodilators, Expectorants, Antitussive agents, Mucolytic agents

1.5 Chemotherapeutic Agents (3 hours)

Penicillins, Cephalosporins, Sulphonamides, Antiviral drugs, Antimalarial agents, Antineoplastic agents

Recommended Books:

1. Introduction to Pharmacology, P.C. Dandiya & S. K. Kulkarni
2. Handbook of Experimental Pharmacology, S. K. Kulkarni
3. A Textbook of General Pharmacology, N.S. Vyawahare & Saloni Vora
4. Essentials of Medical Pharmacology, K.D. Tripathi
5. Lippincott Illustrated Reviews: Pharmacology, Laren Whalen

UNIT 2

2.1 Regulatory Affairs – Introduction (3 hours)

Introduction, brief overview of regulatory authorities and drug related legislation in India - Central Drug Standard Control Organization (CDSO).

2.2 Regulatory Affairs – Indian context. (3 hours)

Drugs and Cosmetics Act, 1940 and its Rules 1945: Objectives, legal definitions of schedules to the Act and Rules pertaining to Import of Drugs, Sale of Drugs and Labeling and Packing of Drugs.

2.3 Indian Regulatory Requirements. (3 hours)

Brief overview of Current Good manufacturing practices (CGMP).
Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP)

2.4 Regulatory Approval Process (3 hours)

Brief overview of approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)

2.5 Patents and Intellectual Property Rights (IPR) (3 hours)

Definition, scope, objectives, brief overview of Patents, Copyrights and Trademarks, sources of patent information

RECOMMENDED BOOKS:

1. Forensic Pharmacy, R.M. Mehta
2. A. Textbook of Forensic Pharmacy, N.K. Jain
3. Pharmaceutical Regulatory Affairs, C.V.S. Subrahmanyam & J. Thimma Setty
4. Drug Regulatory Affairs by Sachin Itkar & N.S. Vyawahare
5. A Concise Textbook of Drug Regulatory Affairs, N. Udupa & Krishnamurthy Bhat

PRACTICAL (2 CREDITS)

Part – 1: Pharmacology

Introduction to the following topics pertaining to the experimental pharmacology, to be discussed and documented in the practical manual.

1. Introduction to experimental pharmacology.
2. Study of laboratory animals: mice, rats, rabbits.
3. Effect of analgesics using Analgesiometer.
4. Screening of anti-convulsant using Electro Convulsiometer.
5. Screening of Muscle relaxants using Rota-Rod apparatus.
6. Study of anxiolytic activity using elevated plus maze method.
7. Study of effect of drugs on isolated heart *(any 2*).

Note: *Animals shall not be used for doing / demonstrating any of the experiments. The following experiments shall be carried- out / demonstrated as the case may be, ONLY with the use of software program(s) such as 'Ex Pharm' or any other suitable software.*

Part – 2: Pharmaceutical Regulatory Affairs:

Prepare a brief checklist and document in the practical manual

1. Good Pharmacy Practices (GPP) – Indian Pharmaceutical association
2. Good Regulatory Practices (GRP)
3. Good Documentation Practices (GDP)
4. Indian patent application.
5. Good Drug Dispensing & Good Storage practice.