ITPD Competency Exam

Pharmaceutical Sciences – Study Guide

Suggested Study References:

PHARMACEUTICAL SCIENCES

Preferred References

• Foye’s Principles of Medicinal Chemistry 7th edition. Thomas L. Lemke. Lippincott Williams & Wilkins; 2012
• Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems
• Handbook of Basic Pharmacokinetics, Including Clinical Applications, 7e (Wolfgang Ritschel, Gregory Kearns)

Other References

• The APhA Complete Review for the FPGEE by Dick R. Gourley
• Pathophysiology of Disease An Introduction to Clinical Medicine, Sixth Edition (Lange Medical Books) by Stephen J. McPhee, Gary D. Hammer

Suggested Learning Objectives:

Medicinal Chemistry

• Given a backbone chemical structure, identify a specific drug, drug class, or therapeutic use.
• Given a specific drug or drug class, identify specific structure activity relationships that allow that drug or drug class to exert its pharmacological effect.
• Describe the key chemical bonding interactions between a drug and receptor.
• Define the principle of a pharmacophore and provide examples.
• Describe the major pathways of drug metabolism including phase I and II metabolism.
• Given a specific drug, delineate its therapeutic class and therapeutic use based on it pharmacology.
• Given a drugs chemical and physical properties, delineate how these properties affect its absorption, metabolism, distribution, and elimination.
• Given a drugs chemical and physical properties, apply these principles to how a drug may be dosed, monitored, or chosen for a specific therapeutic condition.
• Given a drugs pKa and a patient’s PH, calculate the ratio of dissociated to undissociated drug.
Pharmacology

- Recognize the mechanism of action of various cardiovascular medications.
- Recognize the mechanism of action of various cholesterol medications.
- Explain how the mechanism of action of respiratory medications contributes to their efficacy.
- Explain how the mechanism of action of diabetes medications contribute to their efficacy.
- Describe the difference between passive and active transport of drugs into the cell.
- Identify the major differences between parenteral and enteral administration of drugs.
- Describe different routes of drug elimination.
- List side effects and adverse effects of various over-the-counter medications.
- Know the side effects that make some medications unsafe to use in the elderly.
- Understand the relationship between various receptors and mechanism of action of central nervous system medications.
- Explain how antimicrobial agents interact with their targets.
- Recognize and explain the reasoning behind very common drug interactions.
- Identify common food interactions with anticoagulants.
- Identify common lab tests that can be used to monitor safety and efficacy of seizure medications.
- Distinguish between the clinical trial phases of drug study and approval according to the FDA.
- Recall the sources of drugs used in drug development.
- Identify the general steps the drug development process must go through before drugs are tested in humans.

Pharmacognosy & Alternative & Complementary Medications

- Identify the five CAM domains.
- Explain the purpose of 1994 Dietary Supplement and Health Education Act (DSHEA).
- Understand the concept of crude drugs, semi-purified, and purified natural products.
- Recognize specific drug/disease interactions that are present with dietary supplements.

Toxicology

- Define toxicity and toxicokinetics.
- Understand the mechanisms of toxicity.
- Review the impact of toxicity on the pharmacokinetics of a drug.
- Define acute and chronic toxicity.
- Review commonly toxidromes associated with drugs of abuse.
- Describe gastrointestinal decontamination process.
- List commonly used antidotes for the treatment of poisoning or overdose.

Pharmaceutics/Biopharmaceutics

- Review state of matter and how substance change between states.
- Perform calculations using the ideal gas law.
- Describe different types of drug diffusion.
- Explain Fick’s Laws of diffusion and the Noyes-Whitney equation.
- Describe oral bioavailability including how pH and pKa impact the oral bioavailability of a drug.
• Compare and contrast drug delivery systems (oral, parenteral, rectal, topical)
• Calculate drug degradation rates and shelf life based on kinetics
• List the excipients that are used in different dosage forms (capsules, tablets, liquids)
• Review how drug delivery systems are prepared (tablets, capsules, solutions, emulsions, suspensions)

Pharmacokinetics/ Clinical Pharmacokinetics
• Define pharmacokinetics and pharmacodynamics
• Perform calculations related to drug kinetics (plasma drug concentrations, bioavailability, rate of absorption/elimination, volume of distribution, elimination half-life, elimination rate constant, etc.)
• Define bioavailability and bioequivalence as they relate to dosage forms
• Review renal and hepatic clearance of drugs including calculations of excretion ratios and filtration clearance
• Describe renal reabsorption and its impact of pharmacokinetics
• Describe how drug interactions impact ADME
• List instances when therapeutic drug monitoring is valuable
• Understand calculations related to low-therapeutic –index drugs (digoxin, gentamicin, tacrolimus, and cyclosporin)
• List appropriate therapeutic ranges for low-therapeutic-index drugs
• Define the Emax model and and the concentration-dependent phases included in the model

Extemporaneous Compounding
• Describe the United States Pharmacopeia (USP) chapters that relate to pharmaceutical compounding.
• Differentiate between pharmaceutical manufacturing and extemporaneous compounding
• Explain USP regulations for extemporaneous prescriptions
• Review the different types of dosage forms
• Discuss expiration and beyond-use dates for different dosage formulations
• Compare the definitions, purpose, and excipients used in each type of dosage form (liquids, solids, semisolids, and topical preparations.
• Demonstrate the dosage form calculations for capsules, ointments, suppositories, solutions and suspensions.
• Define stability and sterility
• Review ISO clean room classifications