

# CAPE 2013 Supplemental Educational Outcomes

Representing topics related to the Biological Sciences, Chemistry and Pharmaceutics Sections.

## COS-Pharmaceutical Sciences Taskforce Members:

Arbi Nazarian, Ph.D. (Chair), Western University of Health Sciences  
Timothy Bloom, Ph.D. (Biological Sciences), Campbell University  
Marcos Oliveira, Ph.D. (Biological Sciences), University of the Incarnate Word  
Robin Zavod, Ph.D. (Chemistry), Northwestern University-Chicago  
Marc Harrold, Ph.D. (Chemistry), Duquesne University  
Cary Mobley, Ph.D. (Pharmaceutics), University of Florida  
Catherine White, Ph.D. (Pharmaceutics), University of Georgia

## **Anatomy, Physiology and Pathophysiology**

### **Cellular and Molecular Basis of Physiology**

- 1.1.1 Identify various parts and organelles of a cell and their role in cellular physiology.
- 1.1.2 Explain cellular metabolic processes, differentiation and how they are involved in homeostatic physiology of organ systems and related pathological conditions.

### **Central and Peripheral Nervous Systems**

- 1.2.1 Identify parts and homeostatic functioning of the peripheral and central nervous system, such as the peripheral sensory and motor systems, autonomic nervous system, spinal cord and brain.
- 1.2.2 Identify pathological conditions and disease states associated with neurological, psychiatric and neuroendocrine disorders.

### **Endocrine and Reproductive Systems**

- 1.3.1 Identify various parts and homeostatic functioning of endocrine organs, such as the pituitary, thyroid, parathyroid, and adrenal glands. The pancreas and the gonadal endocrine organs shall be represented, as well as the neuroendocrine control via the hypothalamic-pituitary-adrenal and hypothalamic-pituitary-gonadal axes.
- 1.3.2 Describe and identify the pathophysiology of conditions and disease states associated with the endocrine organs.

### **Gastrointestinal System**

- 1.4.1 Identify various organs and explain the homeostatic functioning of the gastrointestinal system, including the mouth, pharynx, esophagus, stomach, intestines and the liver.
- 1.4.2 Describe the pathophysiology of conditions and disease states associated with the gastrointestinal system.

### **Cardiovascular System**

- 1.5.1 Identify various organs and describe the homeostatic functioning of the cardiovascular system, including the heart, the vasculature, circulatory system and the blood.
- 1.5.2 Explain the pathophysiological conditions and disease states associated with the cardiovascular system.

### **Respiratory System**

- 1.6.1 Identify various organelles and explain the homeostatic functioning of the respiratory system including the lungs, bronchus, alveoli and the process of gas exchange.
- 1.6.2 Describe the pathophysiology of conditions and disease states associated with the respiratory system.

### **Renal System**

- 1.7.1 Identify various part and explain the homeostatic functioning of the renal system, including the kidneys, urinary bladder, ureters and urethra.
- 1.7.2 Describe the pathophysiology of conditions and disease states associated with the renal system.

## **Hematologic and Lymphatic Systems**

- 1.8.1 Identify various organs and explain the homeostatic functioning of the hematologic and lymphatic systems, including the various cells in blood, lymphatic tissue, thymus, and spleen.
- 1.8.2 Describe the pathophysiology of conditions and disease states associated with the hematologic and lymphatic systems.

## **Immune System**

- 1.9.1 Identify various cell types and molecules of the immune system and describe the homeostatic functioning of the immune system relevant to detecting and eliminating pathogens and infectious diseases (innate and adaptive immunity).
- 1.9.2 Explain the pathophysiology of conditions and may lead to various immune related disease states (autoimmunity and hypersensitivity).

## **Biology (Biochemistry and Molecular/Cellular Biology)**

### **Structure of the Essential Biological Building Blocks**

- 2.1.1 Describe the functional groups and elements that characterize amino acids, carbohydrate, nucleotides and lipids
- 2.1.2 Evaluate the physical and chemical properties of the functional groups and elements.

### **Structure and Function of Proteins and Enzymes**

- 2.2.1 Describe the different levels of protein structural organization
- 2.2.2 Describe the forces that stabilize proteins and their interaction with other biomolecules.
- 2.2.3 Describe the properties of enzymes, their catalytic strategies, explain the parameters that are used to characterize enzyme activity
- 2.2.4 Evaluate the different types of enzyme inhibitors.

### **Structure of DNA, DNA Damage and Repair, Replication, Transcription and Translation of Genetic Information**

- 2.3.1 Describe the structure of DNA, how it is damaged and the repair mechanisms.
- 2.3.2 Describe how genetic information is organized and expressed within cells.
- 2.3.3 Describe the processes of replication, transcription and translation, comparing them in eukaryotes and prokaryotes.
- 2.3.4 Identify relevant diseases associated with DNA processed and therapeutic targets.

### **Metabolic Pathways for Biosynthesis and Degradation of Carbohydrate, Amino Acids, Nucleotides and Lipids:**

- 2.4.1 Describe the different components of each metabolic pathway
- 2.4.2 Identify the metabolites that integrate different metabolic pathways and explain how metabolic pathways are regulated.
- 2.4.3 Evaluate how changes in metabolic pathways play a role in disease.

### **Signaling Mechanisms, Hormones and Diabetes**

- 2.5.1 Explain how hormones lead to changes in intracellular gene expression and metabolism.
- 2.5.2 Describe the key second messengers and some specific signaling mechanism (e.g. G Protein coupled receptors).

### **Function of Vitamin and Minerals in Metabolism and its Implication in Diet**

- 2.6.1 Describe the essential vitamin and minerals needed for human health
- 2.6.2 Describe the amounts needed in the diet and be able to identify different dietary sources noting their relative richness.
- 2.6.3 Describe the function of vitamins and minerals in enzymatic reactions.

### **Structure and Function of Biological Membranes**

- 2.7.1 Describe the structural components of biological membranes and their physical properties.

- 2.7.2 Describe how proteins are associated with biological membranes and relate how the type of protein association relates to its biological function.
- 2.7.3 Describe the role of biological membranes in drug absorption, distribution and action

### **Recombinant DNA**

- 2.8.1 Describe the process of molecular cloning and how it is used to express proteins for therapeutic use.
- 2.8.2 Describe how molecular techniques are used to diagnose disease and how this leads to effective treatment.

## **Pharmacology**

### **Pharmacokinetic Factors (ADME)**

- 3.1.1 Explain how physiology, dosage form and route of administration affect drug bioavailability.
- 3.1.2 Describe physiological barriers to drug absorption and distribution.
- 3.1.3 Describe the sites and mechanisms of drug metabolism and excretion.
- 3.1.4 Calculate pharmacokinetic parameters such as half-life, volume of distribution, and clearance rates.
- 3.1.5 Describe alterations in pharmacokinetics due to pathophysiological states and the impact co-administration of food and other agents including drugs, nutraceuticals and botanicals.

### **Basis of Receptor-Ligand Interactions and Dose-Responses**

- 3.2.1 Identify a drug as an agonist or antagonist and describe how this impacts the drug's use to achieve a clinical goal.
- 3.2.2 Describe the relationship between drug concentration, receptor binding affinity and clinical response.
- 3.2.3 Compare drugs with regard to potency and efficacy.

### **Macromolecules Acting as Receptors**

- 3.3.1 Identify the different receptor classes, describe their mechanism of action and the biochemical consequences of their activity, and explain how the nature of the receptor impacts the clinical response.
- 3.3.2 Describe the cellular events that follow receptor activation and the means by which this receptor signaling leads to an observable clinical response.

### **Interactions of Drugs with Food, Other Drugs, Nutraceuticals**

- 3.4.1 Describe how drugs' pharmacokinetic and/or pharmacodynamic properties are affected by co-administration of other drugs, food or nutraceuticals.

### **Therapeutic Classes of Drugs**

- 3.5.1 Identify members of a therapeutic class, including the prototypic member.
- 3.5.2 Identify the distinguishing features of members of the class, such as mechanism of action, potency, efficacy, duration of action, risk of toxicity or adverse effect, and special considerations for use.

### **Population Variation Including Pharmacogenomics**

- 3.6.1 Explain variations seen in sub-populations such as infants and the elderly and how this impacts clinical outcomes.
- 3.6.2 Explain the kinds of pharmacogenomic variations seen in the general population, how this variation can be detected in an individual patient and how this variation can alter the clinical use of affected drugs.

### **Toxicity Mechanisms and Kinetics**

- 3.7.1 Describe common anatomical sites and/or physiological/biochemical mechanisms of toxicity and explain strategies to minimize toxicity

# Medicinal Chemistry

## Conduct a Drug Structure Evaluation

- 4.1.1 Identify the chemical and/or pharmacological classification to which a drug belongs.
- 4.1.2 Predict therapeutic applications for individual drugs based on knowledge of chemical and/or pharmacologic classification.
- 4.1.3 Given patient-specific information, select optimal drug within a pharmacologic class based on structure-activity relationships (SAR) and those structural features responsible for binding to biological targets that account for relative drug potencies and receptor affinities.
- 4.1.4 Select optimal drug therapy within a chemical and/or pharmacologic class based on structural features that affect absorption, distribution, metabolism and excretion.
- 4.1.5 Determine the appropriate route(s) of drug administration based on the contribution of specific chemical features to drug solubility in biological fluids and delivery vehicles.
- 4.1.6 Predict and prevent drug-drug interactions, drug-food interactions, drug-herbal interactions, and drug side effects and toxicities by applying knowledge of structural features and other chemical principles.

## Apply Medicinal Chemistry Concepts to Drug Selection

- 4.2.1 Select appropriate drug therapy based on mechanism of drug action via integration of knowledge gained from the drug structure with concepts of organic chemistry, anatomy, physiology, pharmaceuticals, and pharmacology.

## Recommend Changes in Pharmacotherapeutic Regimens Based on Chemical Differences

- 4.3.1 Based on individual patient characteristics and medical conditions, evaluate pharmacotherapeutic options by analyzing chemical features that determine solubility, routes of metabolism, duration of action, and acid-base characteristics.
- 4.3.2 Modify drug therapy regimens based on the evaluation of structural features and chemical properties of drugs that are related to adverse drug reactions, drug-drug interactions, nutritional effects, and lack of efficacy.

## Apply Knowledge of Drug Chemistry to Resolve Drug Therapy Problems

- 4.4.1 Prevent drug-drug interactions by consideration of the pharmacodynamics and pharmacokinetic differences of drugs.
- 4.4.2 Utilizing chemical principles, predict the potential adverse effects that contribute to patient morbidity and non-adherence.
- 4.4.3 Anticipate and prevent problems with drug delivery systems and routes of administration associated with the chemical properties of drugs.
- 4.4.4 Select an appropriate multi-source drug product based on knowledge of the chemical, physical and biochemical properties of a generic drug.

## Use Appropriate Chemical Terminology to Explain Basic Chemical Concepts

- 4.5.1 Effectively communicate the chemical rationale for therapeutic decisions at an appropriate level of understanding for patients, caregivers, and other health professionals.
- 4.5.2 Respond accurately and appropriately to questions related, either directly or indirectly, to drug structure or chemistry that are posed by patients and other health care professionals.

## Maintain Professional Chemical Competence

- 4.6.1 Employ knowledge of structural features to predict mechanisms, adverse effects, metabolism, solubility, acid/base characteristics, potential drug interactions, and therapeutic effects of future drug products.

# Pharmaceutics

## Fundamental Physicochemical Properties

- 5.1.1 Describe the fundamental physicochemical properties that are important for the rational design and formulation of stable dosage forms.
- 5.1.2 Develop causal explanations for the effects of fundamental physicochemical properties on the biopharmaceutical behavior of drugs and dosage forms in the body.
- 5.1.3 In the diagnostic reasoning process, determine and explain any implicated relationships between the drug's physicochemical properties and drug therapy problems.

## Biopharmaceutics

- 5.2.1 Describe the concepts important for understanding and predicting the relationships between the physicochemical properties of the drug, the drug's fate in the body after its administration as a dosage form, and the resulting onset, duration, and intensity of drug action.
- 5.2.2 In the therapeutic reasoning process, assess the biopharmaceutical properties of drug products and drugs during the evaluation of therapeutic alternatives, and during the implementation and monitoring of therapeutic selection(s).

## Chemical and Physical Drug Stability

- 5.3.1 Explain the major mechanisms of drug and dosage form chemical and physical instability, including formulation excipient incompatibilities.
- 5.3.2 Calculate shelf-lives from kinetic data.
- 5.3.3 Predict the effects of formulation and environmental conditions on drug and dosage form degradation.
- 5.3.4 Describe formulation, packaging, and storage approaches for optimizing drug and drug product stability.
- 5.3.5 Assess and recommend solutions for potential chemical and physical stability problems during the evaluation of therapeutic alternatives and during the implementation and monitoring of therapeutic selection(s).
- 5.3.6 Evaluate the effects of significant environmental excursions on drug and drug product stability, and recommend measures to take based on the evaluation.

## Drug Dosage Forms

- 5.4.1 Explain the nature of all pharmaceutical dosage forms, including how they are designed, formulated, manufactured, compounded, and quality-tested.
- 5.4.2 Explain the purposes of excipients in terms suitable for professional and lay persons to understand.
- 5.4.3 In the therapeutic reasoning process, assess and recommend the dosage form(s) and route(s) of administration that will best enable a patient to reach his or her therapeutic goal(s).

## Drug Dosage Form Administration

- 5.5.1 Explain the anatomical and physiological properties important for drug delivery for all parenteral and non-parenteral routes of drug administration.
- 5.5.2 In the diagnostic reasoning process, determine and explain any implicated relationships between the dosage form or its administration and drug therapy problems.
- 5.5.3 In the therapeutic reasoning process, assess and recommend the route(s) and techniques of dosage form administration that will best enable the patient to reach his or her therapeutic goal(s) and minimize untoward effects.
- 5.5.4 Explain and predict the drug's fate in the body following the administration of the dosage form.

## Drug Development, Approval, and Manufacture

- 5.6.1 Explain the drug development and approval process, from drug discovery to post-marketing surveillance.
- 5.6.2 Explain the approval processes for generic and orphan drugs, for compassionate drug use, and for changes in the drug product.
- 5.6.3 Describe the manufacturing processes for sterile and non-sterile dosage forms, the standards for good manufacturing practices, and the elements of compendial standards for chemicals, devices, and drug products.

### **Drug Preparation Compounding**

- 5.7.1 Demonstrate compounding skills for the most common types of sterile and non-sterile preparations.
- 5.7.2 Select the highest quality compounding ingredients. Explain the purposes of excipients.
- 5.7.3 Integrate knowledge of physicochemical properties, biopharmaceutics, and dosage form design and administration with knowledge of pharmacotherapy and the patient's health status, to assess the ability of the proposed compounded preparation to achieve the therapeutic goals for the patient.
- 5.7.4 Explain and follow standards of good compounding practices and compounding regulations.
- 5.7.5 Counsel patients on proper usage of compounded preparations.

### **Control of Drug Delivery**

- 5.8.1 Describe the rationale, approaches, and technologies for the spatial and temporal control of drug delivery, describing examples, advantages, and disadvantages for each route of drug administration.
- 5.8.2 In the therapeutic reasoning process, be able to explain the rationale for selecting controlled delivery products for use in specific patients and the rationale for choosing among different controlled release products of the same drug.
- 5.8.3 Make recommendations for switching between controlled and immediate release drug products during patient therapy.

### **Pharmaceutical Calculations**

- 5.9.1 Demonstrate competence in performing pharmaceutical calculations according to standards that maximize accuracy and precision and that minimize the risk for error.
- 5.9.2 Explain the purpose and goals of each calculation, and the principles underlying the equations and calculation methods.
- 5.9.3 Employ appropriate numbers, units, and descriptive names in all calculations.
- 5.9.4 Utilize methods of estimation and double-checking.
- 5.9.5 Determine that the calculated answer is accurate and logical for its intended purpose or goal.
- 5.9.6 Calculate therapeutic and nutritional needs for the patient and the formulation, dosing, and delivery requirements for products and preparations.

### **Pharmaceutics of Recombinant Therapeutic Proteins and Related Biologics**

- 5.10.1 Explain the production, physicochemical properties, stability, formulation, and delivery of therapeutic proteins that distinguish them from small molecule compounds.
- 5.10.2 Understand the development and approval process for biosimilar biological products.
- 5.10.3 Recommend proper storage, handling, and administration techniques of therapeutic proteins.

## **Pharmacokinetics**

### **Fundamental Physicochemical Properties**

- 6.1.1 Identify and describe the fundamental physicochemical properties of a drug that are important for predicting its absorption, distribution and elimination.
- 6.1.2 Utilize physicochemical properties to explain the pharmacokinetic behavior of a drug.
- 6.1.3 Assess the stability of a drug in the body based on its physicochemical properties.
- 6.1.4 Discuss the relationship between physicochemical properties and route of drug administration.

### **Routes of Administration**

- 6.2.1 Describe how various routes of administration influence the blood/plasma concentration-time profiles and therapeutic response.
- 6.2.2 Discuss advantages/disadvantages of different routes of administration.
- 6.2.3 Assess the appropriateness of route of drug administration selection for achieving the desired therapeutic outcomes.

### **Pharmacokinetic Parameters**

- 6.3.1 Identify and define basic pharmacokinetic parameters which define the time course of drug in the body.

- 6.3.2 Analyze plasma concentration-time data to evaluate the pharmacokinetics of a drug utilizing population data.
- 6.3.3 Analyze plasma concentration-time data to evaluate patient-specific pharmacokinetics utilizing limited data.
- 6.3.4 Assess the pharmacokinetics of a drug from reviewing the literature.
- 6.3.5 Explain how pharmacokinetic parameters influence the concentration-time profiles after various routes of administration and determine its impact on therapeutic response.

### **Dosing Regimens**

- 6.4.1 Determine an appropriate dose and dosing interval utilizing pharmacokinetic population estimates.
- 6.4.2 Determine when and how many blood samples will be needed to assess the efficacy of the dosing regimen.
- 6.4.3 Assess blood level and/or response data to refine a dosing regimen to optimize efficacy and minimize adverse drug reactions.

### **Drug Interactions**

- 6.5.1 Identify and describe mechanisms by which drugs interact with other drugs, foods, nutritional supplements and endogenous substances.
- 6.5.2 Predict potential drug interactions from the drug's pharmacokinetic parameters.
- 6.5.3 Assess the impact of drug interactions on the plasma concentration-time profile and therapeutic response.

### **Dosing in Special Populations**

- 6.6.1 Identify and describe special populations.
- 6.6.2 Explain how physiological processes, which are influenced by disease state, age, etc, affect drug absorption, distribution and elimination.
- 6.6.3 Assess this information to make appropriate adjustments to the dosing regimen to optimize efficacy and minimize adverse drug reactions in these populations.

### **Pharmacogenomics**

- 6.7.1 Identify which pharmacokinetic processes exhibit pharmacogenomics differences.
- 6.7.2 Explain how pharmacogenomic differences influence drug absorption, distribution and elimination.
- 6.7.3 Assess the influence of pharmacogenomic differences on therapeutic outcomes and identify at risk populations.
- 6.7.4 Design individualized dosing regimens based on pharmacogenomic information.
- 6.7.5 Determine appropriate drug monitoring schedules for patients receiving drugs that have known pharmacogenomic differences in one or more pharmacokinetic parameters.