Holland/Adams/Brice/LeBlanc, *Pharmacology for Canadian Pharmacy Technicians, 1st Canadian Edition* Test Bank

Chapter 2 Drug Classification, Regulation, and Approval

Multiple Choice Questions

Question 1

A pharmacy technician student asks what the difference between a therapeutic class and a pharmacologic class is. What is the best response by the technician educator?

1. Therapeutic classification is how the medication produces an effect in the body, whereas pharmacologic classification is how a medication works clinically.
2. Therapeutic classification is how addictive a medication is, whereas pharmacologic classification is how the medication produces an effect in the body.
3. There are no differences between therapeutic and pharmacologic classes.
4. Pharmacologic classification is how the medication produces an effect in the body, whereas therapeutic classification is how a medication works clinically.

Correct Answer: 4

Learning Outcome 2-1: Discuss the basis for placing drugs into therapeutic and pharmacologic classes. Page 15

Question 2

The nurse is preparing to administer a drug that is labeled "used for minor skin irritations." Based on the label, how is this drug classified?

1. By the function
2. By its usefulness
3. By its pharmacologic use
4. By its therapeutic use

Correct Answer: 4

Learning Outcome 2-1: Discuss the basis for placing drugs into therapeutic and pharmacologic classes. Page 15

Question 3

A generic drug takes 60 minutes to produce a therapeutic effect; the brand name drug takes the same amount of time to produce the same effect. This phenomenon is an example of which pharmacological concept?

1. Bioavailability
2. Efficacy
3. Therapeutic effect
4. Adverse effect

Correct Answer: 1

Learning Outcome 2-2: Describe what is meant by a drug's mechanism of action. Page 15

Question 4

The physiologic ability of the drug to reach its target cells and produce its effect is known as which pharmacological concept?

1. Efficacy
2. Bioavailability
3. Therapeutic effect
4. Adverse effect

Correct Answer: 2

Learning Outcome 2-2: Describe what is meant by a drug's mechanism of action. Page 15

Question 5

Which medication change often occurs when a drug demonstrates a wide margin of safety and is used over long periods of time?

1. Prescription-only to over-the-counter (OTC) drug.
2. One classification to a lower, less restrictive one.
3. Traditional drug therapy classification to biologics classification.
4. Therapeutic to effective.

Correct Answer: 1

Learning Outcome 2-3: Describe how drugs are classified as prescription or over-the-counter (OTC) drugs. Page 16-17

Question 6

The pharmacy technician is discussing the advantages over-the-counter (OTC) medications with a patient. Which statements are disadvantages of OTC drugs versus prescription drugs? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. OTC drugs can react with foods, herbal products, and prescriptions, or with other OTC drugs.
2. A patient can obtain OTC drugs more easily than prescription drugs.
3. Self-treatment is sometimes ineffective.
4. Choosing the proper medication for a specific problem can be challenging.
5. OTC drugs are more expensive than prescription drugs.

Correct Answer: 1, 3, 4

Learning Outcome 2-3: Describe how drugs are classified as prescription or over-the-counter (OTC) drugs. Page 16-17

Question 7

A pharmacy technician instructor is teaching fundamental pharmacological content. In helping the students become comfortable with this material, what should the instructor suggest that the student focus on initially?

1. The prototype
2. The generic names
3. The trade names
4. The adverse effects

Correct Answer: 1

Learning Outcome 2-4: Explain the prototype approach to drug classification Page 16

Question 8

Which statements regarding prototype drugs are not accurate? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. A pharmacy technician can apply understanding of the effects of a prototype drug to other drugs in the same class.
2. Understanding the effects of the prototype drug does not help the pharmacy technician to understand the effects of other drugs in the same class.

3. The mechanism of action is different for the prototype drug than for other drugs in the same class.
4. The most commonly used drug in a specific class is always the most widely prescribed drug.
5. Prototype drugs rarely cause drug resistance.

Correct Answer: 2, 3, 4

Learning Outcome 2-4: Explain the prototype approach to drug classification. Page 16

Question 9

Which drug names are examples of trade names? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. Calcium channel blocker
2. Benadryl
3. Loop diuretic
4. Acetaminophen
5. Motrin

Correct Answer: 2, 5

Learning Outcome 2-5: Distinguish between a drug's chemical name, generic name, and trade name. Page 18-19

Question 10

A pharmacy technician is discussing generic and trade drugs with a patient. The patient wants to know why it takes so long for trade drugs to become available in the generic form, which are generally cheaper. What is the pharmacy technicians' best response?

1. It takes 20 years for all pharmaceutical companies to develop a generic version of the drug.
2. It will take 20 years of clinical trials to approve the drug.
3. Sole ownership of a drug allows the pharmaceutical company to earn back the money spent to develop the drug.
4. Animal testing must continue for 10 years, then 10 years of human clinical trials, for a drug to be approved.

Correct Answer: 3

Learning Outcome 2-5: Distinguish between a drug's chemical name, generic name, and trade name. Page 18-19

Question 11

A patient asks the pharmacy technician why the healthcare provider often refers to medications by the generic name instead of by the brand name. What is the best response by the pharmacy technician?

1. The pharmacy will only accept a prescription written with the generic name.
2. The physician prefers to use a more technical-sounding name for medications.
3. There is only one generic name for each medication, but there are often many brand names.
4. The patient needs to ask the physician to explain why medications have so many different names.

Correct Answer: 3

Learning Outcome 2-6: Explain why generic drug names are preferred to other drug names.
Page 19

Question 12

Why are generic names preferred over chemical or trade names when prescribing a medication? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. Chemical names are often complicated and difficult to remember.
2. The generic name can consistently be matched to the active ingredients.
3. There might be multiple trade names for a drug.
4. The generic name is always a shortened version of the chemical name.
5. Chemical names often change.

Correct Answer: 1, 2, 3

Learning Outcome 2-6: Explain why generic drug names are preferred to other drug names.
Page 19

Question 13

A key responsibility of Health Canada would be:

1. Work independent of provincial and territorial governments
2. Ensure the safety and quality of health products and foods
3. Market a drug for sale to Canadians
4. Set prices for all drugs sold in Canada

Correct Answer: 2

Learning Outcome 2-7: Explain the role of Health Canada in the management of Canadian health, drug, and safety issues. Page 20

Question 14

This division of Health Canada authorizes the marketing of pharmaceutical drugs or medical devices after safety, efficacy and quality data is collected from manufacturers:

1. The Biologics and Genetic Therapies Directorate
2. The Therapeutic Products Directorate
3. The Natural Health Products Directorate
4. The Health Products Directorate

Correct Answer: 2

Learning Outcome 2-7: Explain the role of Health Canada in the management of Canadian health, drug, and safety issues. Page 20

Question 15

A scientist is performing research on cellular cultures for a new drug product. At which stage of development is this new drug product?

1. Pre-clinical investigation
2. Clinical investigation
3. Submission of New Drug Application
4. Post marketing surveillance

Correct Answer: 1

Learning Outcome 2-8: Describe the Canadian drug approval process. Page 20-22

Question 16

The purpose of this phase of testing during the drug approval process is to check the effectiveness of the product within large populations of patients. This phase is called:

1. Preclinical investigation
2. Post-marketing surveillance
3. Clinical investigation

4. Health Canada Review

Correct Answer: 3

Learning Outcome 2-8: Describe the Canadian drug approval process. Page 20-22

Question 17

The pharmacist is teaching a patient about prescribed medications. One of the medications is a controlled substance and the patient asks the pharmacist to explain what that means. What is the best response by the pharmacist?

1. A controlled substance is regulated under the Controlled Drugs and Substances Act, and may have many restrictions placed on ordering or refilling this medication.
2. A controlled substance requires both a written prescription and a telephone call from the prescribing practitioner.
3. A controlled substance does not require a prescription to purchase.
4. A controlled substance is always called in to the pharmacy by the practitioner.

Correct Answer: 1

Learning Outcome 2-9: Explain the meaning of the term *controlled substance.* Page 24

Question 18

The pharmacy technician teaches a patient that some drugs are frequently abused, and cause an overwhelming feeling that drives someone to use the drug repeatedly. What topic is the pharmacy technician teaching to this client?

1. Addiction
2. Psychological dependence
3. Physical dependence
4. Dependence

Correct Answer: 1

Learning Outcome 2-9: Explain the meaning of the term *controlled substance.* Page 23

Question 19

Which type of medication would fall under the Controlled Drugs and Substances Act?

1. ibuprofen

2. morphine
3. amoxicillin
4. acetaminophen

Correct Answer: 2

Learning Outcome 2-10: Explain how drugs are scheduled, taking into account the Controlled Drugs and Substances Act (CDSA). Page 24

Question 20

Scheduled drugs are classified by their potential for abuse. Which classification has the highest potential for abuse?

1. V
2. II
3. III
4. I

Correct Answer: 4

Learning Outcome 2-10: Explain how drugs are scheduled, taking into account the Controlled Drugs and Substances Act (CDSA). Page 24

True and False Questions

Question 1

When drugs are grouped together on the basis of how they work within the body pharmacologically, this is referred to as a therapeutic classification.

Correct Answer: False; pharmacological classification

Learning Outcome 2-1: Discuss the basis for placing drugs into therapeutic and pharmacologic classes. Page 15

Question 2

The mechanism of action of a drug is how the medication produces its effects within the body.

Correct Answer: True

Learning Outcome 2-2: Describe what is meant by a drug's mechanism of action. Page 15

Question 3

The symbol ***Pr*** means the drug can only be dispensed with a prescription.

Correct Answer: True

Learning Outcome 2-3: Describe how drugs are classified as prescription or over-the-counter (OTC) drugs. Page 16-17

Question 4

A prototype drug is always the most prescribed type of drug within that drug class.

Correct Answer: False; most understood and usually the first but not necessarily the most used.

Learning Outcome 2-4: Explain the prototype approach to drug classification. Page 16

Question 5

The brand name is usually written in lowercase, whereas the generic name is capitalized.

Correct Answer: False; generic name is written in lowercase while the brand is written capitalized.

Learning Outcome 2-5: Distinguish between a drug's chemical name, generic name, and trade name. Page 18-19

Question 6

There are usually many generic names for the same brand name product.

Correct Answer: False; many brand names for one generic name

Learning Outcome 2-6: Explain why generic drug names are preferred to other drug names. Page 19

Question 7

Health Canada works in partnership with the provincial and territorial governments to maintain and improve the health of Canadians and to ensure medications are safe to use.

Correct Answer: True

Learning Outcome 2-7: Explain the role of Health Canada in the management of Canadian health, drug, and safety issues. Page 20

Question 8

Drug patent protection in Canada lasts 17 years.

Correct Answer: False; 20 years

Learning Outcome 2-8: Describe the Canadian drug approval process. Page 20-22

Question 9

Controlled drugs would include narcotics, such as morphine, controlled drugs, such as methylphenidate, and targeted products, such as diazepam.

Correct Answer: True

Learning Outcome 2-9: Explain the meaning of the term *controlled substance.* Page 23

Question 10

CDSA stands for Controlled Drugs and Supplies Act.

Correct Answer: False; controlled drugs and substances act

Learning Outcome 2-10: Explain how drugs are scheduled, taking into account the Controlled Drugs and Substances Act (CDSA). Page 24

Short Answer Questions

1. Explain how the CDSA is organized into schedules, which schedule is the strictest, and give an example of a drug within that schedule.

ANSWER: The CDSA is organized into 8 schedules with Schedule 1 having the strictest regulations and the most penalty. Examples of drugs within Schedule 1 would be heroin, morphine, and codeine

2. Describe the harmonized drug schedules and give examples of medications found within each schedule.

ANSWER: Schedule 1: are stored in the dispensary and cannot be dispensed without a prescription from a practitioner (example ramipril). Schedule 2: OTC medications that may be harmful to patients if taken in excess or mixed with other drugs, therefore they need more control of their use; stored in the non-patient access area of the pharmacy usually directly behind the case register of the dispensary, and are **available** for pharmacist intervention (example Tylenol # 1). Schedule 3: Immediately in front of the dispensary is the area displaying OTC products that require the intervention of the pharmacist in the patient's selection; because these medications may be harmful to some patient populations, they are stored within view of the pharmacist so that he or she can counsel patients on their use (example: cough and cold products). Unscheduled: can be sold within the intervention of the pharmacist (example small packages of acetaminophen regular strength)

3. What is the difference between the generic name of a drug and a generic drug.

ANSWER: A generic name of the drug is the nonproprietary name given to the drug that is the proper name of the ingredients of the drug. They are usually less complex than the chemical name and easier to remember. Usually there is only one generic name for a drug. However, a generic drug is a generic version, or copy, or the original brand name product the drug was first sold as in Canada. When the patent expires on the original brand name drug after 20 years, a generic version can then be approved to be sold, usually at a lesser price than the original brand name product. To be approved, the company selling the generic version needs to prove to Health Canada that the drug has the same bioavailability and the same drug and strength as the original.