Chapter 02: The Drug Approval Process
Test Bank

MULTIPLE CHOICE

1. The nurse is preparing to administer a schedule II injectable drug and is drawing up half of the contents of a single-use vial. Which nursing action is correct?
a. Ask another nurse to observe and cosign wasting the remaining drug from the vial.
b. Keep the remaining amount in the patient's drawer to give at the next dose.
c. Record the amount unused in the patient's medication record.
d. Dispose of the vial with the remaining drug into a locked collection box.
ANS: A
Schedule II drugs are controlled substances, and all must be accounted for. When wasting a portion of a drug, another nurse should observe and cosign that a drug was wasted.

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2. A patient is prescribed a medication and asks the nurse if the drug is available in a generic form. The nurse understands that a generic medication will have a name that
a. is a registered trademark.
b. is always capitalized.
c. describes the drug's chemical structure.
d. is non-proprietary.
ANS: D
The generic name is the official, non-proprietary name for a drug. The brand name is the trademark name and is always capitalized. The chemical name describes the chemical structure of the drug.

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3. A patient receives a prescription on which the provider has noted that a generic medication may be given. The patient asks the nurse what this means. What will the nurse tell the patient about generic drugs?
a. They contain the same inert ingredients as brand-name drugs.
b. They have chemical structures that are identical to proprietary drugs.
c. They tend to be less expensive than brand-name drugs.
d. They undergo extensive testing before they are marketed.
ANS: C
Generic drugs are approved by the FDA if they are proved to be bioequivalent to the brand-name drug. They tend to be less expensive because manufacturers of these drugs do not have to do the extensive testing required of brand-name drugs before marketing. They are not identical to brand-name drugs and often have different inert ingredients.

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4. The nurse reviews information about a drug and notes the initials "USP" after the drug's official name. The nurse understands that this designation indicates the drug
a. is a controlled substance.
b. is approved by the U.S. Food and Drug Administration (FDA).
c. is available in generic form.
d. meets quality and safety standards.
ANS: D
The "USP" designation is given to drugs that have met high standards for therapeutic use, patient safety, quality, purity, strength, packaging safety, and dosage form by the United States Pharmacopoeia National Formulary. The FDA classifies controlled substances with Roman numerals from I to V. The USP designation does not indicate FDA approval. The USP designation does not indicate generic availability.

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5. The nurse is preparing to give a medication to a child. The child's parent asks whether the drug is safe for children. How will the nurse respond to the parent?
a. "Drugs are tested on adults and safe doses for children are based on weights compared to adult weights."
b. "Drugs are deemed safe for children over time when repeated use proves effectiveness and safety."
c. "Drugs are tested for both efficacy and safety in children in order to be marketed for pediatric use."
d. "Drugs are tested on children in postmarketing studies and on a limited basis."
ANS: C
The Pediatric Research Equity Act requires drug manufacturers to test drugs on children.

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6. Which law(s) govern all drug administration by nurses?
a. Drug Regulation and Reform Act
b. FDA Amendments Act
c. Nurse Practice Acts
d. The Controlled Substances Act
ANS: C
Each state's Nurse Practice Act identifies how nurses administer medications. The other acts govern how drugs are marketed and tested.

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7. The nurse administers a drug and miscalculates the dose by placing the decimal place one space to the right, resulting in a 10-fold overdose and the death of the patient. What offense does this represent?
a. Malfeasance
b. Malpractice
c. Misfeasance
d. Nonfeasance
ANS: C
Misfeasance is negligence in giving either the wrong drug or the wrong dose, resulting in the death of the patient.

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8. The nurse is busy and neglects to give a drug to a patient resulting in the patient's death. What offense does this represent?
a. Malfeasance
b. Malpractice
c. Misfeasance
d. Nonfeasance
ANS: D
Nonfeasance is omitting a drug dose, resulting in the patient's death.

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9. A patient is taking methadone as part of a heroin withdrawal program. The nurse understands that, in this instance, methadone is classified as which drug schedule?
a. C-I
b. C-II
c. C-III
d. C-V
ANS: B
Methadone is a category II drug, with a high potential for drug abuse.

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10. The nurse is preparing to administer a combination drug containing acetaminophen and codeine. The nurse knows that this drug is classified as which drug schedule?
a. C-II
b. C-III
c. C-IV
d. C-V
ANS: B
Codeine is normally a category II drug, except when it is part of a combination product such as with acetaminophen, making it a category III drug.

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MULTIPLE RESPONSE

1. Which are responsibilities of the U.S. Food and Drug Administration (FDA)? (Select all that apply.)
a. To ensure a drug has accurate labeling
b. To ensure a drug is affordable
c. To ensure a drug is effective
d. To ensure a drug is free from adverse reactions
e. To ensure a drug is tested for harmful effects
ANS: A, C, E
The FDA ensures that drugs are labeled correctly, that they are tested and proven effective for the conditions they are marketed to treat, and that they are tested for harmful effects. The FDA does not ensure affordability or freedom from adverse reactions, although these must be noted in drug information materials.

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