Understanding Pharmacology for Health Professionals, 5e (Turley) Chapter 2 Drug Design, Testing, Manufacturing, and Marketing

2.1 Multiple-Choice Questions

1) Which name accurately describes the molecular structure of a drug and distinguishes it from

all other drugs?

A) brand name

B) chemical name

C) generic name

D) trade name

Answer: B

Explanation: A) The brand name does not to describe molecular structure.

C) The generic name does not describe molecular structure.

D) The trade name does not describe molecular structure.

2) In the distant past, without the use of computers, designing a new drug was _____.

A) a quick process, done by just repositioning molecules

B) a slow process of trial and error

C) not done, because drug companies didn't know about molecular structures

D) easy to do, by using models of wood and wire

Answer: B

Explanation: A) Without the use of computers, designing a new drug was not a quick process.

C) Even before computers, drug companies knew about molecular structures.

D) There was only one way that was known.

3) Using computers to design new drugs involves _____, which is the study of the chemical structures of drugs and their actions at the molecular level within a cell.

A) genetics

B) molecular pharmacology

C) pharmacodynamics

D) recombinant DNA technology

Answer: B

Explanation: A) Genetics is the basis for gene therapy, not designing new drugs at the molecular level.

C) Pharmacodynamics has to do with drug effects based on time and dose; it does not involve computers.

D) Recombinant DNA technology uses enzymes in test tubes, not computers, to create new drugs.

4) In 1982, which drug became the first recombinant DNA technology drug to be approved by the FDA?

A) the semisynthetic penicillin known as ampicillin, which was fermented in vats

B) diazepam (Valium)

C) human insulin (Humulin)

D) Taxol (chemotherapy drug)

Answer: C

Explanation: A) Penicillin and ampicillin were not created by recombinant DNA technology. B) Diazepam (Valium) was created from the molecular structure of chlordiazepoxide, not by recombinant DNA technology.

D) Taxol was originally derived from the needles of the Pacific yew tree, not from recombinant DNA technology.

5) Information from the human genome has led to the development of the subspecialty areas of ______ in research and drug design.

A) pharmacogenetics and pharmacogenomics

B) pharmacodynamics and pharmacology

C) recombinant DNA technology and computers

D) pharmacology and stem cell therapy

Answer: A

Explanation: B) Pharmacology is not a subspecialty area of research and drug design.

C) Information on the human genome has not led to the development of either recombinant DNA technology or computers.

D) Pharmacology is not a subspecialty area of research and drug design.

6) From the moment of its discovery or design, every drug has a ______ name that is assigned by the International Union of Pure and Applied Chemistry (IUPAC).

A) brand

B) chemical

C) generic

D) trade

Answer: B

Explanation: A) The brand name, or trade name, is created by the drug company, not assigned by the IUPAC.

C) The drug company, working together with the United States Adopted Names (USAN) Council, not the IUPAC, determines a drug's generic name.

D) The trade name, or brand name, is created by the drug company, not assigned by the IUPAC.

7) Which of the following is registered with the U.S. Patent Office as a registered trademark?

A) chemical name

B) generic name

C) molecular structure

D) trade name

Answer: D

Explanation: A) A drug's chemical name is assigned by the IUPAC, not the U.S. Patent Office. B) The drug company, working together with the United States Adopted Names (USAN) Council, not the U.S. Patent Office, determines a drug's generic name.

C) A drug's molecular structure is part of the drug's makeup, and is not registered as a trademark.

8) Which of the following involves using a drug on several hundred or several thousand ill patients in exactly the same way as it will be used once it is on the market?

A) clinical trials, phase I

B) clinical trials, phase II

C) clinical trials, phase III

D) in vivo testing

Answer: C

Explanation: A) During phase I, about 10 to 100 healthy volunteers are used to study a drug. C) In phase II, the drug is given to about 50 to 500 patients who actually have the disease that the drug is intended to treat.

D) In vivo testing is a general designation for any testing done on animals and humans.

9) Each drug is assigned a 10-digit code, broken up into three segments. Which of the following is NOT information that can be obtained from the 10-digit code?

A) the name of the drug company

B) the drug category

C) the drug's specific strength/dose

D) the package size and type

Answer: B

Explanation: A) The first segment of the 10-digit code does identify the drug company.

C) The second segment of the 10-digit code does identify the drug's specific strength/dose.

D) The third segment of the 10-digit code does identify the drug's package size and type.

10) Once the FDA gives final approval for drug marketing, the drug company creates a

B) generic name

C) molecular name

D) trade name

Answer: D

Explanation: A) The chemical name is assigned by the IUPAC, not the drug company.

B) The generic name is developed by both the drug company and the U.S. Adopted Names Council before the FDA gives final approval for marketing.

C) A drug does not have a molecular name, but uses a chemical name instead to describe the drug's molecular structure.

A) chemical name

11) The drug name that is a registered trademark is the _____.

A) generic name

B) chemical name

C) trade name

D) all of the above

Answer: C

Explanation: A) The generic name is not a registered trademark.

B) The chemical name is not a registered trademark.

D) Only one of the answers is correct.

12) All of the following are reasons why the trade names of some drugs are spelled in a certain way. Identify the reason that is NOT true.

A) The spelling of the trade name indicates the length of the drug's patent.

B) The spelling of the trade name indicates the drug's source.

C) The spelling of the trade name indicates the disease process being treated.

D) The spelling of the trade name indicates how often the drug should be taken. Answer: A

Explanation: A) The drug patent is NOT reflected in the drug name spelling.

B) The spelling of some trade names DO indicate the drug's source.

C) The spelling of some trade names DO indicate the disease process the drug is used to treat.

D) The spelling of some trade names DO indicate how often the drug should be taken.

13) The trade name of the drug Lithobid was selected to indicate _____.

A) the name of the drug company

B) how often the drug is to be given

C) the amount of the active ingredient

D) the disease the drug is used to treat

Answer: B

Explanation: A) The name Lithobid does not indicate the name of the drug company

C) The name Lithobid does not indicate the amount of the active ingredient

D) The name Lithobid does not indicate the disease the drug is used to treat.

14) Drugs can be created or designed using all of the following techniques, EXCEPT _____.

A) discovery in nature

B) observing the toxic effects

C) computer-aided design

D) recombinant DNA technology

Answer: B

Explanation: A) Drugs ARE created by discovery in nature.

B) The presence of toxic effects of a drug does not lead to a drug being created or designed.

C) Drugs ARE created by computer-aided design.

D) Drugs ARE created by recombinant DNA technology.

15) In clinical trials, the control group receives the _____. A) trade name drug B) placebo C) chemical name drug D) generic name drug Answer: B Explanation: A) The control group does not receive the trade name drug. C) The control group does not receive the chemical name drug. D) The control group does not receive the generic name drug. 16) The patent on a new drug is in effect for _____ years. A) 5 B) 12 C) 17 D) 23 Answer: C Explanation: A) A drug patent is not in effect for five years.

B) A drug patent is not in effect for 12 years.

D) A drug patent is not in effect for 23 years.

17) There are _____ phases of human testing for new drugs.

A) two

B) three

C) five

D) seven

Answer: B

Explanation: A) There are more than two phases to human testing.

C) There are fewer than five phases to human testing.

D) There are fewer than seven phases to human testing.

18) Recombinant DNA technology involves ______.

A) gene splicing

B) genetic engineering

C) human DNA spliced into a bacterial cell

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

19) In vivo testing is ______.
A) testing that is done in test tubes
B) similar to *in vitro* testing
C) done prior to *in vitro* testing
D) none of the above
Answer: D
Explanation: A) In vivo testing is not done in test tubes.
B) In vivo testing is not similar to *in vitro* testing.
C) In vivo testing is not done prior to *in vitro* testing.

20) Inert ingredients in a drug _____

A) include fillers to shape a tablet

B) can affect drug bioavailability

C) also include binders

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

C) This is true, but it is not the only correct answer.

21) The United States Adopted Names (USAN) Council _____.

A) gives the final approval for marketing of a drug

B) works with the drug company to determine the generic name for a drug

C) selects the generic and trade names for all drugs

D) names all new chemical and molecular substances

Answer: B

Explanation: A) The FDA, not the USAN, gives final approval for marketing of a drug.

C) The USAN does not select the trade names for drugs.

D) The International Union of Pure and Applied Chemistry (IUPAC), not the USAN, assigns the chemical name.

22) Which of the following statements is FALSE?

A) There is only one generic drug name related to a specific chemical name.

B) The trade name is specifically designed to be easy for physicians and patients to remember.

C) The drug's original trade name can be used by other companies after the patent expires.

D) The spellings of generic drugs that belong to the same drug category often reflect their similar chemical structure.

Answer: C

Explanation: A) This statement is true.

B) This statement is true.

C) This is a false statement Only the drug company that created that trade name can use that trade name.

D) This statement is true.

23) What does the therapeutic index indicate?

A) the therapeutic potential for this new drug

B) the margin of safety between the therapeutic and toxic doses

C) the drug's effectiveness and likely approval by the FDA

D) the bioavailability of the drug

Answer: B

Explanation: A) The therapeutic potential for the drug is evaluated by the drug company and the FDA and is not related to the therapeutic index.

C) The therapeutic index relates to the drug's margin of safety, not whether the drug will be effective and approved.

D) The therapeutic index relates to the drug's margin of safety, not its bioavailability.

24) The first recombinant DNA technology drug approved by the FDA was ______.

A) an over-the-counter drug

B) a drug for HIV

C) a drug from pregnant mares' urine

D) human insulin

Answer: D

Explanation: A) Recombinant DNA technology is not used to produce over-the-counter drugs.B) The first drug for HIV was AZT, but it was not produced by recombinant DNA technology.C) The drug from pregnant mares' urine, a natural source (not recombinant DNA technology), is Premarin.

D) Human insulin (Humulin) was the first.

25) This drug contains a double-strength dose, as shown by its trade name.

A) Bactrim DS

B) Kay Ciel

C) Pronestyl-SR

D) Tylenol w/ Codeine No. 2

Answer: A

Explanation: B) This trade name indicates the ingredients in the drug–potassium (K) and chloride (Cl).

C) This trade name indicates that this is a sustained-release drug (SR).

D) This trade name indicates the amount of a particular active ingredient (codeine).

26) The Human Genome Project _____

A) led to the development of computer-aided design of drugs

B) mapped all 3.2 billion parts of the human genome

C) is the third part of clinical testing after *in vivo* testing

D) determined what the names of new genetic drugs should be

Answer: B

Explanation: A) Computer-aided design of drugs was in use before the Human Genome Project was undertaken.

C) The Human Genome Project is not part of clinical trials testing.

D) The Human Genome Project is not related to the naming of drugs.

27) The chemical name of a drug ____

A) is too lengthy and complicated for everyday use by healthcare professionals

B) is only used by researchers and consumers

C) is the same as the generic name of the drug

D) all of the above

Answer: A

Explanation: B) The chemical name is only used by drug companies and researchers, never by consumers.

C) The chemical name is not the same as the generic name of a drug.

D) Only one of the answers is correct.

28) All of these trade names reflect the disease that the drugs are used to treat, EXCEPT

A) Sudafed

B) Pepcid

C) Azmacort

D) Rythmol

Answer: A

Explanation: A) Sudafed is simplification of the generic name.

B) This DOES reflect the disease that the drug is used to treat: peptic ulcers.

C) This does reflect the disease that the drug is used to treat: asthma.

D) This does reflect the disease that the drug is used to treat: an irregular heart rhythm.

29) What incentive does the FDA give to drug companies that agree to do clinical trials of their drugs on children?

A) a cash-back refund

B) speeding up the process for getting a trademark for the drug

C) a six-month extension on the new drug patent

D) allowing the drug companies to market the drug to children

Answer: C

Explanation: A) The FDA does not give a cash-back refund to drug companies.

B) A trademark is issued by the U.S. Patent Office, not the FDA.

D) Drugs are not marketed to children.

30) An example of a placebo is _____

A) an injection of sterile normal saline

B) a genetically engineered drug

C) a sugar pill

D) A and C

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) A placebo is a drug that has no therapeutic effect. Genetically engineered drugs always have a therapeutic effect.

31) A moisture-absorbing packet of silica gel, known as _____, is something that would be added to a drug container to keep tablets from deteriorating.

A) the half-life

B) a placebo

C) an isomer

D) a desiccant

Answer: D

Explanation: A) The half-life is a period of time, not a substance.

B) A placebo does not keep tablets from deteriorating.

C) An isomer does not keep tablets from deteriorating.

32) Post-marketing surveillance _____

A) is a type of direct-to-consumer advertising

B) is performed by the Federal Trade Commission

C) involves adding a National Drug Code to each drug package

D) is done by the drug company and the FDA to monitor drug safety

Answer: D

Explanation: A) Direct-to-consumer advertising is not related to post-marketing surveillance. B) The Federal Trade Commission regulates the advertising of over-the-counter drugs, but does not do post-marketing surveillance.

C) There is a National Drug Code on each drug package, but it is not related to post-marketing surveillance.

33) All of the following are examples of new drugs discovered in the environment, EXCEPT

A) a placebo used in double-blind studies

B) a chemotherapy drug derived from yew tree needles

C) cephalosporin antibiotic drugs from a fungus in a sewer outlet

D) an antituberculosis drug from the stomach of a sick chicken

Answer: A

Explanation: A) A placebo is not discovered in the environment.

B) This is an example of a drug discovered in the environment.

C) This is an example of a drug discovered in the environment.

D) This is an example of a drug discovered in the environment.

34) A dextrorotary drug _____.

A) is an isomer

B) has a right-facing image for its molecular structure

C) example is that of dextromethorphan

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

35) When designing drugs, a computer can _____

A) display the molecular structure of any drug in its database

B) identify chemicals that would probably not be successful in treating a particular disease, which saves time and money

which saves time and money

C) rotate any molecule in three dimensions on the computer screen

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

C) This is true, but it is not the only correct answer.

36) Using recombinant DNA technology, which substance has been made into a recombinant DNA technology drug?

A) clotting factors

B) erythropoietin

C) human growth factor

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

C) This is true, but it is not the only correct answer.

37) Slight molecular changes to a drug can significantly affect its _____.

A) absorption and metabolism

B) half-life

C) Therapeutic effect and side effects

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) This is true, but it is not the only correct answer.

C) This is true, but it is not the only correct answer.

38) The FDA evaluates a drug before approving it. This evaluation includes a review of

A) the drug company's documentation

B) consumer comments about the drug

C) drug's risks and benefits

D) A and C

Answer: D

Explanation: A) This is true, but it is not the only correct answer.

B) The FDA does not review consumer comments before approving a drug.

39) Why would a physician give a patient a free sample of a drug?

A) To give away what the drug representatives gave them

B) To help patients save money

C) To allow the patient to try a limited supply to see if it worked

D) To fulfill FDA requirements

Answer: C

Explanation: A) This is not the reason.

B) This is not the reason.

D) There are no FDA requirements about free drug samples.

40) What can the FDA do when it receives reports of adverse drug effects for a particular drug? A) The FDA can red flag a drug.

B) The FDA can have the drug company expand the warning label on the drug.

C) The FDA can withdraw the drug from the market.

D) B and C

Answer: D

Explanation: A) There is no such procedure as a red flag.

B) This is true, but it is not the only correct answer.

C) This is true, but it is not the only correct answer.

41) The drug Byetta, which is used to treat diabetes mellitus, is derived from _____.

A) coal mining

B) saliva of the Gila monster

C) venom of the cone snail

D) recombinant DNA technology

Answer: B

Explanation: A) Coal tar, not Byetta, is derived from coal mining.

C) Prialt, not Byetta, is derived from venom of the cone snail.

D) Byetta was not created with recombinant DNA technology.

42) The first drug to be created with recombinant DNA technology was _____.

A) Humulin insulin

B) Allegra

C) rDNA

D) hydrochlorothiazide

Answer: A

Explanation: B) Allegra was not created with recombinant DNA technology.

C) This is not a drug; it is an abbreviation for recombinant DNA technology.

D) This drug was not created with recombinant DNA technology.

43) The trade name K-Lyte/Cl tells us that this drug contains A) iron and glucose B) potassium and chloride C) a double strength dose of the drug D) chloride and snail venom Answer: B Explanation: A) It does not contain iron and glucose. C) It does not contain a double-strength dose. D) It does not contain chloride and snail venom. 44) The half-life of a drug can be increased because of _____. A) liver or kidney disease B) particulate matter C) animal studies D) the presence of desiccant Answer: A Explanation: B) Particulate matter does not affect the half-life. C) Animal studies help determine the half-life but do not increase it. D) Desiccant absorbs moisture from the drug; it does not increase its half-life. 45) Pharmacokinetics involves _____. A) absorption of a drug

B) distribution of a drug

C) metabolism of a drug

D) all of the above

Answer: D

Explanation: A) This is true, but it is not the only correct statement.

B) This is true, but it is not the only correct statement.

C) This is true, but it is not the only correct statement.

46) A drug tablet may include all of the following, EXCEPT _____.

A) binders and fillers

B) desiccant

C) preservatives

D) antioxidants and buffers

Answer: B

Explanation: A) A tablet CAN contain binders and fillers.

B) Desiccant is NOT part of the tablet; it is placed in the drug bottle.

C) A tablet CAN contain preservatives.

D) A tablet CAN contain antioxidants and buffers.

2.2 True/False Questions

1) An isomer is a drug that has the same chemical formula as another drug, but has those atoms arranged in a different way. Answer: TRUE

2) Once a drug has received its final approval from the FDA, its ingredients, doses, manufacturing process, labeling, and packaging cannot be changed. Answer: TRUE

3) The advertising of both prescription and OTC drugs is regulated by the FDA. Answer: FALSE Explanation: The marketing and advertising of over-the-counter drugs are regulated by the Federal Trade Commission.

4) The FDA has standards for the spelling of trade name drug, and drug companies must follow them.

Answer: FALSE

Explanation: There are no standards for the spelling of trade name drugs.

5) No matter how a drug was originally discovered or designed, it must be thoroughly tested by the FDA before it can be marketed.

Answer: FALSE

Explanation: It must be thoroughly tested by the drug company, not the FDA.

6) Generic drugs and trade name drugs that are in the same drug form and drug strength--even if they are from different drug companies-must contain exactly the same amount of active ingredient.

Answer: TRUE

7) A drug company is protected by a 17-year patent on any new drug that is approved by the FDA. However, part of the 17-year patent period is used up during the testing process. Answer: TRUE

8) Once a drug has been approved by the FDA, the drug can continue to be marketed indefinitely because it has received FDA approval.

Answer: FALSE

Explanation: Just because a drug has been approved does not guarantee it will remain on the market over time.

9) Many drugs still in use today were originally taken from plant, animal, or mineral sources hundreds or even thousands of years ago. Answer: TRUE 10) The Recombinant DNA Advisory Committee is a group of physicians and pharmacists who review the clinical trials of genetically engineered new drugs and make recommendations to the FDA.

Answer: TRUE

11) The animal phase of drug testing precedes testing on humans. Answer: TRUE

12) The pharmacodynamics of a drug are tested during the human phase of drug testing. Answer: FALSE Explanation: The pharmacodynamics are tested during the animal phase.

13) The higher the number of the therapeutic index, the more desirable it is, because it indicates that the drug has a wide margin of safety. Answer: TRUE

14) While it is physiologically impossible for a placebo to exert any pharmacological effect, patients often report a decrease in certain types of symptoms after taking a placebo. Answer: TRUE

15) In a double-blind study, every patient receives both the drug and a placebo.

Answer: FALSE

Explanation: Double-blind means neither the physician or the patient knows whether he/she gets the drug of a placebo.

16) In a double-blind study, the physician-investigator is the only one who knows which patients are taking a drug and which patients are taking a placebo.Answer: FALSEExplanation: Even the physician-investigator does not know.

17) A placebo uses the power of suggestion to produce changes in the body that mimic the pharmacologic action of an actual drug. Answer: TRUE

18) A drug company may evaluate thousands of different chemicals before finding one that moves successfully through all phases of testing and is finally approved by the FDA for release and marketing. Answer: TRUE

19) Individual genes from DNA can be manipulated to create drugs. Answer: TRUE

20) The Human Genome Project allowed drug researchers to begin gene therapy to replace defective genes in the body. Answer: TRUE 21) The ending *-olol* is common to generic beta-blocker drugs. Answer: TRUE

22) It is not uncommon for a patient who is given a therapeutic dose of digoxin (Lanoxin) to exhibit symptoms of toxicity. Answer: TRUE

23) Drugs that are successfully tested in animals will always perform well when given to humans.

Answer: FALSE Explanation: Animal studies do not always show how well a drug will perform in humans.

24) A drug can be approved to treat one thing and then, after further clinical trials, can also be approved to treat something completely different. Answer: TRUE

25) The label of a drug does not need to contain an expiration date printed on it, because drugs never expire.Answer: FALSEExplanation: Drugs DO expire.

26) Advertisements of drugs to consumers are heavily weighted toward prescription drugs for chronic diseases that require long-term treatment. Answer: TRUE

27) MedWatch is the FDA safety information and adverse event reporting system on the Internet. Answer: TRUE

2.3 Short Answer Questions

1) When animal studies are completed, the drug company submits an IND application to the	ie
FDA. The abbreviation IND stands for	
Answer: Investigational New Drug	

2) There are three phases of human testing, which together are known as _____. Answer: clinical drug trials

3) A ______, a drug that has no pharmacologic effect, is often used in double-blind studies during phase III clinical trials. Answer: placebo

4) Once phase III is completed, the drug company submits all of its documentation on the drug to the FDA in the form of a NDA. The abbreviation NDA stands for _____. Answer: New Drug Application

5) DTC marketing has become common, beginning with magazine ads and moving to television. The abbreviation DTC stands for _____. Answer: direct to consumer

6) The ______ of the active drug ingredient can be particularly crucial in drugs with a low therapeutic index. Answer: bioavailability

7) Define these abbreviations.

- FDA _____
- DTC _____
- ΤI _____
- IND _____
- NDC _____

rDNA

Answer: Food and Drug Administration, direct-to-consumer [marketing], therapeutic index, Investigational New Drug, National Drug Code, recombinant DNA

8) Darlene Ellis has been prescribed the drug Nasalcrom. From the trade name of the drug, you can tell that the drug is used to treat this part of her body: _____. Answer: nose

9) When the FDA removes a drug from the market because of manufacturing defects, this is known as a drug . Answer: recall

10) ______ is the knowledge of how genetic makeup of different people affects their responses to drugs.

Answer: pharmacogenetics

11) The trade name is also known as the _____ name because it implies brand recognition and customer loyalty. Answer: brand

12) Define these abbreviations.

Fe Κ LA

SR

Answer: iron, potassium, long-acting, slow-release

13) When volunteers answer a newspaper ad for a clinical drug trial, it is mandatory that they give informed ______ to participate in the trial. Answer: consent

14) A single dose of a drug can be placed in an individually sealed ______ that contains a bubble of clear plastic over the capsule or tablet. Answer: blister pack

15) The marketing and advertising of over-the-counter drugs is regulated by the _____. Answer: Federal Trade Commission

2.4 Matching Questions

Group A

Match the terms with their proper definitions.

A) shows the number of animals who responded or do not respond to a drug and at what doses. B) the dose at which 50 percent of the animals tested had toxic levels of the drug

C) the time required for drug levels in the serum to decrease from 100 percent to 50 percent.

D) relative margin of safety between the dose that produces a therapeutic effect and the dose that produces a lethal effect in animals

E) the dose at which 50 percent of the animals tested show a therapeutic response to the drug

1) frequency distribution curve

- 2) half-life
- 3) median effective dose (ED50)
- 4) median toxicity dose (TD50)
- 5) therapeutic index (TI)

Answers: 1) A 2) C 3) E 4) B 5) D

Group B

Match the drug name with its discovery process.

A) a totally new chemical derived from molecular manipulation of a drug that is already in use B) a totally new chemical substance discovered in the environment, from plants, animals, or the soil

C) a totally new chemical created through genetic DNA manipulation

- 6) diazepam
- 7) Aranesp
- 8) fexofenadine (Allegra)
- 9) human insulin (Humulin)
- 10) streptomycin

Answers: 6) A 7) A 8) A 9) C 10) B

2.5 Essay Questions

1) The FDA sometimes removes certain batches of drugs from the market because of manufacturing defects. Name three manufacturing defects that would be the reasons for a drug recall.

Answer: 1. The drug does not contain the correct amount of active ingredient. 2. The drug does not remain stable until its expiration date. 3. The drug is contaminated with particulate matter from the manufacturing process.

2) Briefly explain the difference between *in vivo* testing and *in vitro* testing.

Answer: Chemical analysis of a drug done in a laboratory in test tubes is known as *in vitro* testing. Testing carried out in animals or humans is known as *in vivo* testing.

3) Briefly explain how a double-blind study is performed using a control group, a placebo, and drug group.

Answer: Double-blind studies with the drug and a **placebo** are performed, in which neither the patients nor the physician-investigators know which patients are receiving the drug and which patients (the **control group**) are receiving the drug.