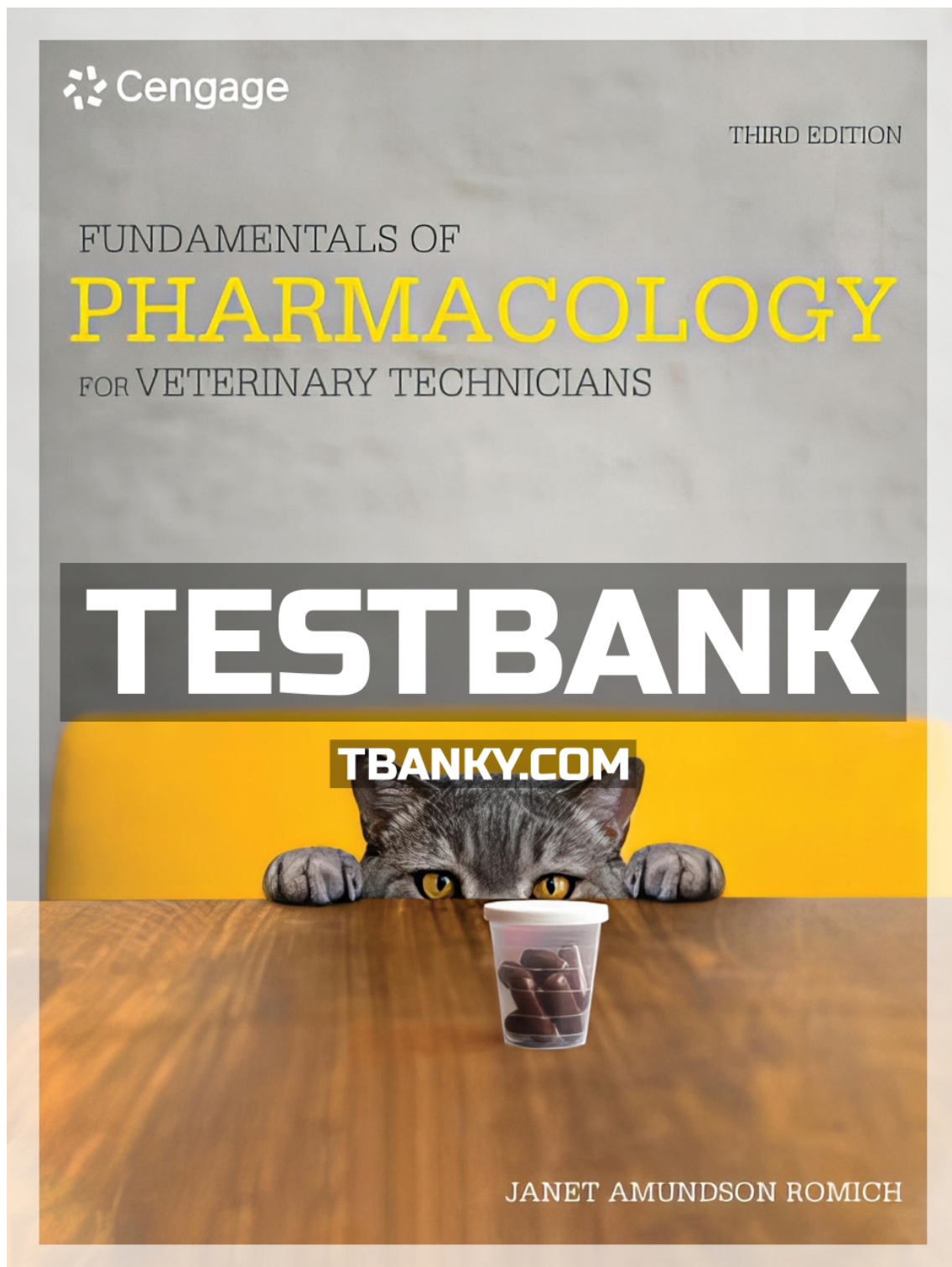


**TEST BANK FOR FUNDAMENTALS OF  
PHARMACOLOGY FOR VETERINARY  
TECHNICIANS 3RD EDITION ROMICH ISBN  
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Name: \_\_\_\_\_ Class: \_\_\_\_\_ Date: \_\_\_\_\_

**01 A Brief History of Veterinary Pharmacology**

1. Which animal population had the first outbreak of disease creating the field of veterinary pharmacology?

- a. Elephants
- b. Cattle
- c. Dogs
- d. Birds

ANSWER: b

2. Before it was veterinary pharmacology what was it called?

- a. Pharmakeutikos
- b. Epizootics
- c. Genomia
- d. *Materia medica*

ANSWER: d

3. What term is used for the physiological movement of drugs?

- a. Pharmacokinetics
- b. Pharmacotherapeutics
- c. Pharmacodynamics
- d. Pharmacotherapy

ANSWER: a

4. What term is used for investigating how a sick animal responds to drugs?

- a. Pharmacogenetics
- b. Pharmacotherapeutics
- c. Pharmacogenomics
- d. Pharmacotherapy

ANSWER: b

5. \_\_\_\_\_ is the term used for the study of the impact of genetic variation on drug effects.

- a. Pharmacogenetics
- b. Pharmacotherapeutics
- c. Pharmacodynamics
- d. Pharmacogenomics

ANSWER: d

6. Which of the following is not covered under FDA regulations?

- a. Biologics
- b. Food additives
- c. Pesticides
- d. Cosmetics

ANSWER: a

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**01 A Brief History of Veterinary Pharmacology**

7. Which of the following statements is true?

- a. The U.S. Food and Drug Administration (FDA) became a government agency to enforce the federal Pure Food and Drugs Act of 1938.
- b. The FDA's CVM prohibits the sale and use of a drug that would cause animals to suffer serious health problems, unless it will relieve a different more serious condition.
- c. FDA approval of a particular drug is based on the drug's therapeutic effects and adverse effects in many test animals.
- d. It is important to note that FDA regulations do cover certain medically significant compounds known as therapeutic agents derived from living organisms, such as vaccines, antibodies, and toxoids.

**ANSWER:** c

8. Which drugs may be purchased by a client without a prescription?

- a. Extra-label
- b. Over-the-counter
- c. Controlled substance
- d. Biologics

**ANSWER:** b

9. Which OTC should not be given to cats because it contains aspirin?

- a. Subsalicylate
- b. Chondroitin
- c. Glucosamine
- d. Zeniquin

**ANSWER:** a

10. Which guidelines give the authority for extra-label drug use?

- a. DEA
- b. USDA
- c. FDA
- d. AMDUCA

**ANSWER:** d

11. When is it allowable to use an extra-label drug?

- a. If it will improve an animal's productivity
- b. If it is less expensive than an approved drug
- c. If there is no FDA-approved drug to treat the animal
- d. If there is not yet an established VCPR

**ANSWER:** c

12. Which type of drug is considered dangerous because of its potential for human abuse or misuse?

- a. Extra-label
- b. Prescription
- c. Over-the-counter

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- d. Controlled substance

ANSWER: d

13. Which agency controls the use of controlled substances?

- a. USDA
- b. FDA
- c. DEA
- d. AVMA

ANSWER: c

14. What happens when a controlled substance is combined with another drug?

- a. It is illegal to combine higher-level and lower-level controlled substances.
- b. It must be classified as both a lower-level and a higher-level substance.
- c. It is classified as the higher-level controlled substance.
- d. It is classified as the lower-level controlled substance.

ANSWER: d

15. The risk of residues is increased by improper drug use and failure to follow the \_\_\_\_\_.

- a. dosing schedule
- b. withdrawal time
- c. disposal protocol
- d. inventory controls

ANSWER: b

16. Where can you find a list of all withdrawal times and drugs approved for use in food-producing animals?

- a. VFD
- b. FARAD
- c. DEA
- d. FDA-CVM

ANSWER: b

17. When is a VCPR considered valid or established?

- a. If the client pays the veterinarian's bill
- b. If a referral is made to a veterinarian based on the owner's assessment
- c. If follow-up visits are required
- d. If the veterinarian has assumed the responsibility for making clinical judgments

ANSWER: d

18. During which type of telehealth is a diagnosis not given?

- a. Telemedicine
- b. Telerriage
- c. Teleconsulting

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- d. Telemonitoring

ANSWER: b

19. When can medical advice be given outside of a VCPR using telehealth?

- a. Telemedicine
- b. Teleradiology
- c. Teleconsulting
- d. Telemonitoring

ANSWER: a

20. Which level of controlled substance has no currently acceptable medical use?

- a. Schedule I
- b. Schedule II
- c. Schedule III
- d. Schedule IV

ANSWER: a

21. Which of the following drugs is a schedule II (C-II)?

- a. Marijuana
- b. Phenobarbital
- c. Morphine
- d. Testosterone

ANSWER: c

22. What is the difference between a schedule I and schedule II drug?

- a. Schedule I drugs have no accepted medical use and schedule II drugs do.
- b. Schedule I drugs have accepted medical use and schedule II drugs do not.
- c. Schedule I drugs have a high potential for abuse and schedule II drugs have a low potential for abuse.
- d. Schedule II drugs have a high potential for abuse and schedule I drugs have a low potential for abuse.

ANSWER: a

23. The veterinarian has prescribed an acetaminophen/codeine combination for pain for your dog. What level substance is that drug?

- a. Schedule I
- b. Schedule II
- c. Schedule III
- d. Schedule IV

ANSWER: c

24. Which level of controlled substance has a low potential for abuse?

- a. C-I
- b. C-II

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c. C-IV

d. C-V

ANSWER: d

25. How often do veterinarians have to register with the DEA, if they wish to prescribe controlled substances?

a. Annually

b. Bi-annually

c. Triennially

d. Every five years

ANSWER: c

Name: \_\_\_\_\_ Class: \_\_\_\_\_ Date: \_\_\_\_\_

**02 Veterinary Drug Development and Control**

1. How long does it take on average for testing before a new veterinary drug appears on the market?

- a. One year
- b. Three years
- c. Five years
- d. Seven years

**ANSWER:** d

2. During which stage of drug development is a drug approved or rejected?

- a. Stage I
- b. Stage II
- c. Stage III
- d. Stage IV

**ANSWER:** c

3. Which regulatory agency develops new uses of existing pesticides?

- a. USDA
- b. EPA
- c. FDA
- d. DEA

**ANSWER:** b

4. When can preclinical studies begin?

- a. Stage I
- b. Stage II
- c. Stage III
- d. Stage IV

**ANSWER:** b

5. What is another name for stability studies?

- a. Shelf life studies
- b. Clinical trials
- c. Post-approval monitoring
- d. Surveillance studies

**ANSWER:** a

6. What test is done to determine the dosage at which a drug induces organ or tissue damage resulting in permanent injury or death?

- a. Margin of safety
- b. Therapeutic indexing
- c. Systems-oriented screening
- d. Toxicity evaluation

**ANSWER:** d

Name: \_\_\_\_\_ Class: \_\_\_\_\_ Date: \_\_\_\_\_

**02 Veterinary Drug Development and Control**

7. Which agency requires that all drugs be tested for adverse effects before approval?

- a. USDA
- b. EPA
- c. FDA
- d. DEA

ANSWER: c

8. If a serious adverse reaction occurs on a \_\_\_\_\_ then the manufacturer will most likely terminate drug testing.

- a. special test
- b. short-term toxicity test
- c. reproductive test
- d. long-term test

ANSWER: b

9. If a manufacturer wants to see if a drug causes cancerous tumors, which test would be conducted?

- a. Carcinogenicity test
- b. Special test
- c. Reproductive test
- d. Teratogenicity test

ANSWER: a

10. Which of the following statements is true?

- a. Drugs that kill with a small dose need further evaluation.
- b. Only drugs that are highly lethal need to include the lethal dose on their marketing materials.
- c. The effective dose is the dose that produces the desired effect.
- d. A dose can be called effective only if the amount of the test drug caused a defined effect in 75 percent of the animals.

ANSWER: c

11. What percentage of the animals receiving a drug must die in order for researchers to identify the lethal dose?

- a. 10 percent
- b. 25 percent
- c. 50 percent
- d. 75 percent

ANSWER: c

12. What is the lethal dose of Valium® in mice?

- a. 720 mg/kg given orally
- b. 500 mg/kg given orally
- c. 2,000 mg/kg given orally
- d. 100 mg/kg given orally

ANSWER: a



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**02 Veterinary Drug Development and Control**

13. A dose can be called effective only if the amount of the test drug causes a defined effect in \_\_\_\_\_ of the animals that receive it.

- a. 10 percent
- b. 25 percent
- c. 50 percent
- d. 75 percent

ANSWER: c

14. What value is determined by comparing the drug's LD<sub>50</sub> and its ED<sub>50</sub>?

- a. Long-term toxicity
- b. Systems-oriented screen
- c. Chronic study
- d. Therapeutic index

ANSWER: d

15. How long are tests conducted before they can be labeled non-carcinogenic?

- a. Three months
- b. Six months
- c. Three years
- d. Six years

ANSWER: b

16. What do systems-oriented screens test?

- a. Toxicity
- b. Physiological systems
- c. Therapeutic indices
- d. Margins of safety

ANSWER: b

17. If there is a small difference between an effective dose and a lethal dose then there is a \_\_\_\_\_.

- a. narrow therapeutic index
- b. broad therapeutic index
- c. narrow shelf life
- d. broad shelf life

ANSWER: a

18. A greater therapeutic index is represented by a(n) \_\_\_\_\_ number.

- a. equal
- b. larger
- c. smaller
- d. zero

ANSWER: b

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**02 Veterinary Drug Development and Control**

19. When calculating the therapeutic index, what is used as the measure of toxicity?

- a. The effective dose
- b. The lethal dose
- c. The margin of safety
- d. Toxic evaluation

**ANSWER:** b

20. What is monitored during therapeutic drug therapy?

- a. Temperature
- b. Plasma levels
- c. Blood pressure
- d. Bone marrow

**ANSWER:** b

21. If the LD<sub>50</sub> and ED<sub>50</sub> values are known for a given drug, how can you determine the therapeutic index?

- a. By subtracting the LD<sub>50</sub> value by the ED<sub>50</sub> value
- b. By adding the LD<sub>50</sub> value by the ED<sub>50</sub> value
- c. By multiplying the LD<sub>50</sub> value by the ED<sub>50</sub> value
- d. By dividing the LD<sub>50</sub> value by the ED<sub>50</sub> value

**ANSWER:** d

22. When researchers are testing for fetal defects, they are testing for which adverse effect?

- a. Carcinogenicity
- b. Teratogenicity
- c. Reproductivity
- d. Toxicity

**ANSWER:** b

23. After a drug is approved, is any further testing done?

- a. No, once approved all testing is stopped.
- b. No, because further testing may reveal adverse effects.
- c. Yes, long-term toxicity tests continue for up to two years.
- d. Yes, if the company so decides to continue testing.

**ANSWER:** c

24. Who can report an adverse reaction to the FDA?

- a. Veterinarians
- b. Animal owners
- c. Manufacturers
- d. All of the choices are correct.

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**02 Veterinary Drug Development and Control**

ANSWER: d

25. When will the FDA approve a drug for general use even if it can cause birth defects?
- a. If the risk to the fetus is so small in number that it is unlikely to occur
  - b. If the benefits of the drug are far greater than the risk to the fetus
  - c. If the manufacturer can demonstrate that the adverse effects no longer exist in certain breeds
  - d. If the therapeutic index has narrowed to such a number that the FDA is now comfortable with the risk

ANSWER: b

## Chapter 1 Review

### Matching

*Match the term or phrase with its proper definition.*

1. **d** drugs that can be purchased without a prescription
2. **b** drugs considered dangerous because of their potential for human abuse or misuse
3. **f** drugs that can be obtained only through a veterinarian or via a prescription
4. **g** drugs used in a manner not specifically described on the FDA-approved label
5. **a** study of a drug's mechanism of action and its biological and physiological effects
6. **c** study of absorption, distribution, metabolism, and elimination of drugs
7. **e** the treatment of disease with medicines
8. **h** computer-based system containing information on how to avoid drug, pesticide, and environmental contaminant residue problems
9. **j** the law that allows extra-label use of a drug under certain conditions
10. **i** agency that ensures that approved veterinary medicines are relatively safe for animals

### Multiple Choice

*Choose the one best answer.*

11. Which of the following virtual care options must have a valid VCPR?
  - a. Telemedicine**
  - b. Teleadvising
  - c. Telerriage
  - d. Teleconsulting
12. A person studying how the body absorbs, uses, and eliminates codeine is engaged in the pharmacological specialty called \_\_\_\_\_.
  - a. pharmacotherapeutics
  - b. pharmacodynamics
  - c. pharmacokinetics**
  - d. pharmaconeurology
13. Controlled substances must \_\_\_\_\_.
  - a. be kept in a locked cabinet or safe
  - b. have orders, receipts, uses, and thefts recorded
  - c. be ordered by veterinarians who register triennially with the DEA
  - d. All of the above are correct**
14. The higher the schedule number (e.g., V vs. I) of a controlled-substance drug, the \_\_\_\_\_.
  - a. higher the risk for human abuse potential
  - b. more questionable its manufacture is
  - c. lower the risk for human abuse potential**
  - d. lesser medical value it has
15. Which statement regarding pharmacogenetics is true?
  - a. Adverse drug reactions are unique to the drug and not the patient.
  - b. Pharmacogenetics can explain all adverse drug reactions seen in veterinary patients.
  - c. Pharmacogenetics explains some adverse drug reactions seen in veterinary patients.**

- d. Adverse drug reactions seen only in certain breeds are based on breeders' imaginations.
16. An example of an OTC veterinary drug is \_\_\_\_\_.
- a. phenobarbital, a C-IV controlled substance
  - b. marbofloxacin, an antibiotic
  - c. **fipronil, a topical flea and tick product**
  - d. acetaminophen, a fever-reducing medication

### True/False

Circle "a" for true or "b" for false.

17. Prescription drugs are limited to use by or under the supervision of a veterinarian or physician.
- a. **True**
  - b. False
18. The majority of veterinary drugs in use during the early 1900s were found naturally in plants.
- a. **True**
  - b. False
19. The major requirement of the Food, Drug, and Cosmetic Act of 1938 is the requirement of drug safety.
- a. **True**
  - b. False
20. Diazepam is an example of a schedule I drug.
- a. True
  - b. **False**
21. Over-the-counter drugs are approved for human use only by the FDA.
- a. **True**
  - b. False
22. All drugs are used to treat sick animals.
- a. True
  - b. **False**

### Case Studies

23. An owner of a 12-year-old male/neutered (M/N) German Shepherd Dog calls the clinic because her dog has been vomiting blood. She says the dog was fine yesterday and has been more active since she began giving aspirin to relieve the pain associated with the dog's arthritis. You explain to the owner that aspirin can cause gastrointestinal upset and that some adverse signs the animal may show are vomiting and diarrhea. The owner says that it is impossible for the aspirin to be causing the dog to vomit blood, because aspirin can be purchased without a prescription.
- a. What do you tell this owner?
- OTC drugs are available without a prescription, but that does not mean that they are without potential side effects. This owner should be questioned about how much aspirin he is giving his**

dog, what type of aspirin he is giving his dog, and when he is giving his dog aspirin. Even if the owner is giving his dog an amount of aspirin within the acceptable levels, there may still be side effects seen in individual animals. OTC drug side effects may also be seen more frequently in animals on a variety of medications, so this owner should be questioned about what other medications the animal may be taking.

b. What advice can you give this owner?

The owner needs to understand that all medication, even OTC drugs, can cause side effects. Owners should consult with veterinarians before giving animals any medication. Some cautions to consider when patients are given OTC drugs include the following:

- The use of OTC drugs may delay professional diagnosis and treatment of disease.
- Signs of disease may be masked by OTC drugs, making diagnosis of disease more complicated.
- The patient must be given the proper amount of drug at the proper frequency for the proper duration. This may be difficult to do for animals since labels and instructions for OTC drugs are usually written for people.
- Patients may be on prescription drugs or other OTC drugs that may react with a particular OTC drug.
- Inactive ingredients in OTC drugs may interact with other drugs or may themselves cause adverse reactions.
- Clients may see a positive effect of the OTC drug (known as the placebo effect), which makes the owner continue to give the OTC drug even though it is no longer needed.
- There is an overdose potential with OTC drugs, especially if clients are giving their animals more than one OTC drug with similar active ingredients.

24. A large animal veterinarian wants to administer flunixin meglumine intramuscularly (IM) to a dairy cow to control her fever. Flunixin meglumine is approved for use intravenously (IV) in beef and dairy cattle to control fever and inflammation. The veterinarian feels that it is easier to give this drug IM versus IV and that the convenience of administration route is a valid reason to use this in an extra-label fashion.

a. Is the veterinarian correct? Why or why not?

**No, AMDUCA states that extra-label drug use must be for therapeutic reasons only and not for convenience.**

b. Why is administering a drug by a non-FDA approved route a concern in food-producing animals?

**It is true that drugs are deemed extra-label when they are used in a different species; for a different reason (medical condition); at a different dosage, frequency, or route of administration; or a different withdrawal time is used; however, extra-label drug use must be for therapeutic reasons only. This extra-label use also must not result in drug residues in food-producing animals. Drug residues can be monitored and prevented by proper identification and tracking of food-producing animals and determining an extended period for drug withdrawal before marketing milk, meat, or eggs from treated animals.**

### Critical Thinking Questions

25. Why would a veterinary technician need or want a clear understanding of the historical development and current practices of drug development and usage?

**Understanding the historical development of drug development helps veterinary professionals have confidence in dispensing and recommending drugs, allows veterinary professionals to stay informed of drug safety with the continual monitoring and reporting of adverse drug reactions, and provides the knowledge of what is and is not investigated as far as drug safety is concerned**

(e.g., reproductive effects). It helps the veterinary professional explain why we may still see adverse effects when administering FDA-approved drugs and identify the difference between an acceptable side effect versus a response that is contraindicated.

26. Why are controlled substances an issue in veterinary practice when the controlled substance rating is based on the potential for human abuse, and the veterinary community is not treating humans? **Animals do not have the ability to “abuse” drugs like humans do, but they may develop a dependence on some of the side effects of a particular drug. The more important reason that controlled substance ratings are used in veterinary medicine is because of the risk of substance abuse by the veterinary staff and members of the public who may seek out veterinary controlled substances. Veterinary clinics are common sources of burglaries by those trying to gain access to controlled substances. The same rules for safe storage of controlled substances apply whether the drug is used in a veterinary or human setting.**

**Veterinary clinic break-ins, including those in which safes are taken because they are easier to take than open, are being seen in increasing numbers.**

27. How can telehealth change the practice of veterinary medicine? **Currently, the method in which the veterinarian–client–patient relationship (VCPR) can be established is by a hands-on physical exam. Once a VCPR is established, veterinary professionals can use telemedicine tools to monitor patients. For example, a veterinary technician can have an online discussion with a client about their pet’s postoperative wound healing and if the level of pain control is adequate which would include photos and videos of the patient instead of relying solely on the owner’s descriptions. Telehealth can also improve the care of oncology patients. Once the animal is examined at an appointment with both the veterinarian and veterinary technician present, a VCPR is established and the veterinary technician can work independently and remotely with the client to conduct quality-of-life consultation appointments. Using photos and videos, veterinary technicians can assess the patient’s comfort level in the home environment and give advice to the client while avoiding a potentially stressful clinic visit for the patient.**

**Another scenario in which veterinary technicians can use telehealth is via communication with the veterinary clinic. For example, a veterinary technician has an app service that connects him/her with veterinary practices requesting a house call. The veterinary technician goes on a home visit to examine a cat with a history of cardiomyopathy and an existing VCPR with the veterinarian who dispatched her to the patient’s home. The veterinary technician performs a physical exam and reports the patient’s data (bilateral crackles upon thoracic auscultation, distension of the jugular veins, and a systolic blood pressure of 180 mmHg) to the veterinarian from the practice using the app service. The veterinarian then uses the information obtained from the veterinary technician to diagnose the developed pulmonary edema secondary to cardiomyopathy in the patient.**

## Chapter 2 Review

### Matching

*Match the term or abbreviation with its proper definition.*

1. **b** NADA
2. **d** FDA
3. **f** EPA
4. **e** USDA
5. **j** INAD
6. **a** clinical trials
7. **c** preclinical studies
8. **i** therapeutic index
9. **g** systems-oriented screen
10. **h** effective dose

### Multiple Choice

*Choose the one best answer.*

11. Which therapeutic index is the safest of those listed below?
  - a. 2
  - b. 10
  - c. 20
  - d. 30**
12. The margin of safety is another name for the \_\_\_\_\_.
  - a. effective dose
  - b. lethal dose
  - c. safety parameter
  - d. therapeutic index**
13. LD<sub>50</sub>/ED<sub>50</sub> is the mathematical expression of what value?
  - a. The lethal dose
  - b. The effective dose
  - c. The margin of safety**
  - d. The mortality dose
14. A drug that has a margin of safety of 75 is \_\_\_\_\_.
  - a. safer than a drug whose margin of safety is 5**
  - b. less safe than a drug whose margin of safety is 5
  - c. ineffective at low doses
  - d. not marketable in the United States
15. How long a drug remains stable and effective for use is known as its \_\_\_\_\_.
  - a. half-life
  - b. shelf life**
  - c. effective life
  - d. special test life
16. The term used to describe the capacity to cause birth defects is \_\_\_\_\_.



- a. reproductivity
- b. carcinogenicity
- c. **teratogenicity**
- d. theriogenicity

### True/False

Circle “a” for true or “b” for false.

17. The FDA is responsible for approval of all chemicals dispensed by veterinarians.
  - a. True
  - b. **False**
  
18. Once the FDA approves a drug, it is no longer monitored for safety and effectiveness because it has already undergone extensive testing prior to approval.
  - a. True
  - b. **False**
  
19. Satisfactory clinical trial results allow scientists to file a NADA with the FDA.
  - a. **True**
  - b. False
  
20. A drug with a narrow margin of safety means less of the drug is needed to produce the lethal dose in comparison to a drug with a wide margin of safety.
  - a. **True**
  - b. False

### Case Studies

21. A client calls your office to ask a question regarding his animal’s medication. He is currently giving his dog one antibiotic tablet twice daily to treat a bacterial skin infection. The client is going on vacation and is wondering if his dog sitter could give four antibiotic tablets once every two days instead of one antibiotic tablet four times over two days. Because the total dose over the two days would be the same, the client thinks this is acceptable and would save the dog sitter some time and trouble.  
 Is it acceptable to give this dog its entire two-day dose at one time? Why or why not? Relate your answer to testing or test results performed by drug companies to get FDA approval.  
**Even though the total dose per two-day period is the same with both regimens, it is not recommended to give the entire dose at once. Since extensive testing is done on drugs to determine their effectiveness at a particular dose with minimal side effects, it is not advised to quadruple this dose for the client’s convenience. This dog could develop toxic side effects unique to this drug if the dose given is greater than this drug’s therapeutic index. This is especially true if this drug has a narrow therapeutic index.**
  
22. You are working at a research facility that conducts research on new drugs. A pharmaceutical company has developed a new antibiotic in its laboratory and wants the new antibiotic to be tested on research mice at your facility. In Phase I, a group of mice will be infected with bacteria to produce pneumonia. After developing pneumonia, some mice will be administered a single dosage level (from three available drug dosages) of the experimental antibiotic intravenously while other mice will not receive the experimental antibiotic (this group is a control group). After 24 hours, the mice

will be euthanized and lung tissue samples will be cultured for bacterial growth. Any antibiotic that demonstrates efficacy in the experimental mice will be advanced to *in vivo* (in living organisms) toxicity investigation (Phase II). In Phase II, each compound that was deemed effective in Phase I will be administered in 2-fold increasing dosages to groups of three mice. The entire group will be monitored (heart and respiratory rates, urine output, body temperature, mentation status) at least every hour for 8 hours and then every 6 hours for 24 hours. If toxicity is observed at one of the dosage levels, the treatment will be repeated at that dosage and half of that dosage to confirm the maximal tolerated dose. Someone asks you what benefits can be gained from this type of testing. What will be your response?

**As people who care about animals, we want the drugs we administer to them to be safe and effective. It may seem cruel to test drugs on animals, but there are regulations and policies in place to reduce the number of animals tested and ensure that animals are treated humanely during these studies. There is a significant amount of governmental (regulatory), institutional, and veterinary oversight of research in animals that has yielded relevant data used to develop drugs to treat many animals with effective and safe drugs.**

There are four stages of testing required during drug development. The process starts with preliminary studies to determine if the drug produces the intended effect(s) and whether it has toxic properties. These tests may be done on computers, in laboratory media, or on simple organisms such as bacteria or fungi. If the preliminary studies are favorable and significant, a series of preclinical studies and clinical trials are performed on laboratory animals to examine toxicity effects, measure movement of the drug into, through and out of the body and determine the appropriate dosage of the drug. Safety and effectiveness tests include short-term and long-term toxicity studies and special tests of immediate drug reactions, organ system damage, reproductive effects, carcinogenicity, and teratogenicity. The preclinical studies and clinical trials are part of phase I. Phase II monitors the drug's effectiveness and helps determine the therapeutic index (margin of safety). When sufficient animal data demonstrate the new drug's relative safety and effectiveness, the process enters phase III in which researchers submit an Investigational New Animal Drug (INAD) application to the FDA (or Experimental Use Permit (EUP) with the EPA if it is a pesticide) or an appropriate application with the Animal and Plant Health Inspection Services (APHIS) of the USDA if it is a biologic. Phase III monitors efficacy and adverse reactions and is used to compare the new drug to existing treatments. If phase III is successful, the drug is approved for marketing by the FDA.

### Critical Thinking Questions

23. What is the significance of a drug's therapeutic index to a veterinary technician?

**The therapeutic index is used to describe the safety of a drug. The therapeutic index is determined by comparing the drug's lethal dose and its effective dose ( $LD_{50}/ED_{50}$ ). Drugs with a large therapeutic index tend to be safer than drugs with a small therapeutic index. Drugs with a small therapeutic index that are administered to animals should be monitored closely for any signs of toxic side effects. This increased level of monitoring may include performing additional blood tests or diagnostic procedures or observing physical signs like vomiting and diarrhea.**

24. Why is the term "adverse drug effects" more appropriate than "side effects" when describing unintended effects of a drug?

**The term "side effects" implies that these effects are somehow separate from the therapeutic effects. The term "adverse drug effects" implies that these effects are drug effects, not something on the side. For example, polyuria/polydipsia (PU/PD) can occur with glucocorticoid use. PU/PD**

**cannot be separated off to the side from the therapeutic benefit of glucocorticoids; they go hand-in-hand. The PU/PD is just an undesirable result of treatment with glucocorticoids.**

25. Why is stage four of veterinary drug development important?

**Stage four is the postmarketing surveillance stage and is important because both the company (with financial interests in the drug's production) and the government (without financial interest in the drug's production) are committed to making sure the drug is manufactured safely for as long as it is produced. Monitoring a drug over many years with large populations of animals provides extensive data that can be used to determine if that the drug is still effective as manufactured. If any adverse drug reactions are discovered the drug can be withdrawn from the market for the safety of patients.**