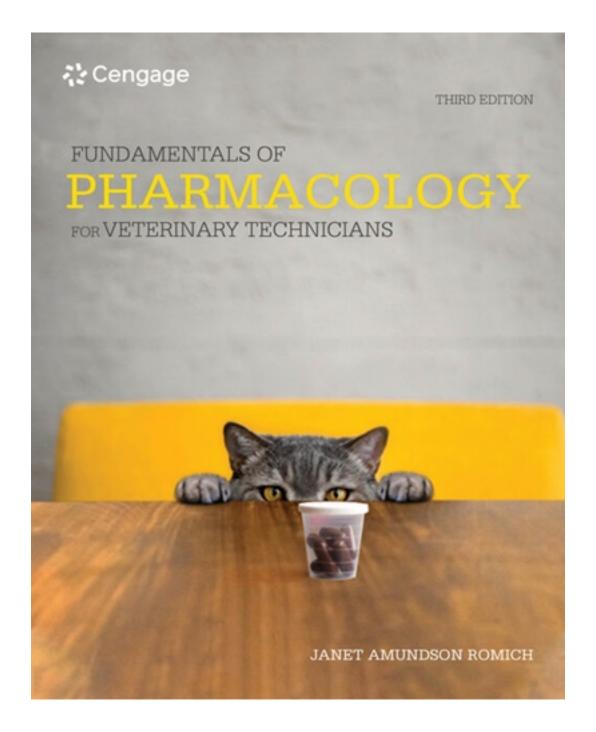
# Test Bank for Fundamentals of Pharmacology for Veterinary Technicians 3rd Edition by Romich

# CLICK HERE TO ACCESS COMPLETE Test Bank



# Test Bank

| Class:                                     | Date:  |
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| reak of disease creating the field of vete | rinary pharmacology?   |
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| vement of drugs?                           |  |
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| r FDA regulations?                         |  |
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| <u>l</u> r                                 | reak of disease creating the field of veter that was it called?  The ment of drugs?  The ck animal responds to drugs?  The impact of genetic variation on drug ending the field of veter than the fiel |

ANSWER: a

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|---|--|----------------------------------|
| Name:   | Class:                                       | Date:                            |
| 01 A Brief History of Veterinary P  | harmacology                                  |                                  |
| 7. Which of the following statement   | s is true?                                   |                                  |
| <ul> <li>a. The U.S. Food and Drug Admi<br/>and Drugs Act of 1938.</li> </ul> | inistration (FDA) became a government agency | to enforce the federal Pure Food |

- 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. Subsalisylate
  - b. Chondroitin
  - c. Glucososamine
  - 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 of misuse?
  - a. Extra-label
  - b. Prescription
  - c. Over-the-counter

| Name:  | Class:                                      | Date:                   |
|--|---|-------------------------|
| 01 A Brief History of Veterinary Pharn             | nacology                                    |                         |
| d. Controlled substance                            |   |                         |
| ANSWER: d  |   |                         |
| 13. Which agency controls the use of con           | itrolled substances?                        |                         |
| a. USDA  |   |                         |
| b. FDA   |   |                         |
| c. DEA   |   |                         |
| d. AVMA  |   |                         |
| ANSWER: c  |   |                         |
| 14. What happens when a controlled sub             | stance is combined with another drug?       |                         |
| ${f a}.$ It is illegal to combine higher-level     | l and lower-level controlled substances.    |                         |
| b. It must be classified as both a lowe            | er-level and a higher-level substance.      |                         |
| c. It is classified as the higher-level co         | ontrolled substance.                        |                         |
| d. It is classified as the lower-level co          | ontrolled substance.                        |                         |
| ANSWER: d  |   |                         |
| 15. The risk of residues is increased by im        | nproper 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 withdr        | rawal 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 ea          | stablished?                                 |                         |
| ${f a}.$ If the client pays the veterinarian's     | s bill                                      |                         |
| b. If a referral is made to a veterinari           | ian based on the owner's assessment         |                         |
| c. If follow-up visits are required                |   |                         |
| $d.\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $         | e responsibility for making clinical judgme | ents                    |
| ANSWER: d  |   |                         |
| $18.\ { m During}$ which type of telehealth is a d | iagnosis not given?                         |                         |
| a. Telemedicine                                    |   |                         |
| b. Teletriage                                      |   |                         |

 $c. \ {\sf Teleconsulting}$ 

| Name:   | Class:                                    | Date:                                  |
|---|---|--|
| 01 A Brief History of Veterinary Pharm  | acology                                   |  |
| d. Telemonitoring   |   |  |
| ANSWER: b   |   |  |
| 19. When can medical advice be given out a. Telemedicine  | side of a VCPR using telehealth?          |  |
| b. Teletriage   |   |  |
| c. Teleconsulting   |   |  |
| d. Telemonitoring   |   |  |
| ANSWER: a   |   |  |
| <ul> <li>20. Which level of controlled substance has a. Schedule I</li> <li>b. Schedule II</li> <li>c. Schedule III</li> <li>d. Schedule IV</li> </ul>        | as no currently acceptable medical use?   |  |
| ANSWER: a   |   |  |
| <ul> <li>21. Which of the following drugs is a scheoa. Marijuana</li> <li>b. Phenobarbital</li> <li>c. Morphine</li> <li>d. Testosterone</li> </ul> ANSWER: c | dule II (C-II)?                           |  |
| 22. What is the difference between a sche   | <del>-</del>                              |  |
|   | medical use and schedule II drugs do.     |  |
|   | edical use and schedule II drugs do not.  |  |
| •   | tial for abuse and schedule II drugs have | •                                      |
| a. Schedule II drugs have a high poter ANSWER: a  | ntial for abuse and schedule I drugs have | a low potential for abuse.             |
| 23. The veterinarian has prescribed an ace is that drug?  a. Schedule I  b. Schedule II  c. Schedule III  | etaminophen/codeine combination for pa    | ain for your dog. What level substance |
| d. Schedule IV  |   |  |
| ANSWER: c   |   |  |
| 24. Which level of controlled substance ha<br>a. C-I<br>b. C-II   | as a low potential for abuse?             |  |

| Name:   | Class:                            | Date:                         |
|---|-----------------------------------|-------------------------------|
| 01 A Brief History of Veterinary Pharmacolo                 | <u>gy</u>                         |                               |
| c. C-IV   |                                   |                               |
| d. C-V  |                                   |                               |
| ANSWER: d   |                                   |                               |
| 25. How often do veterinarians have to register a. Annually | with the DEA, if they wish to pre | scribe controlled substances? |
| b. Bi-annually  |                                   |                               |
| c. Triennially  |                                   |                               |
| d. Every five years   |                                   |                               |
| ANSWER: c   |                                   |                               |

| Name:  | Class:                                 | Date:                              |
|--|--|------------------------------------|
| 02 Veterinary Drug Development and Co                        | <u>ntrol</u>                           |                                    |
| 1. How long does it take on average for test a. One year     | ing before a new veterinary drug app   | ears on the market?                |
| 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 u                    | ses of existing pesticides?            |                                    |
| 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 studie                 | s?                                     |                                    |
| a. Shelf life studies  |  |                                    |
| b. Clinical trials   |  |                                    |
| c. Post-approval monitoring                                  |  |                                    |
| d. Surveillance studies                                      |  |                                    |
| ANSWER: a  |  |                                    |
| 6. What test is done to determine the dosa; injury or death? | ge at which a drug induces organ or ti | ssue damage resulting in permanent |
| a. Margin of safety  |  |                                    |
| b. Therapeutic indexing                                      |  |                                    |
| c. Systems-oriented screening                                |  |                                    |
| d. Toxicity evaluation                                       |  |                                    |
| ANSWER: d  |  |                                    |

| Name:   | Class:                                 | Date:                               |
|---|--|-------------------------------------|
| 02 Veterinary Drug Development and Con  | trol                                   |                                     |
| 7. Which agency requires that all drugs be te a. USDA                                   | sted for adverse effects before appro  | oval?                               |
| b. EPA  |  |                                     |
| c. FDA  |  |                                     |
| d. DEA  |  |                                     |
| ANSWER: c   |  |                                     |
| 8. If a serious adverse reaction occurs on a $\_$ a. special test                       | then the manufacturer will mo          | ost likely terminate drug testing.  |
| b. short-term toxicity test   |  |                                     |
| c. reproductive test  |  |                                     |
| d. long-term test   |  |                                     |
| ANSWER: b   |  |                                     |
| 9. If a manufacturer wants to see if a drug ca a. Carcinogenicity test                  | uses cancerous tumors, which test w    | rould be conducted?                 |
| 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 |  |                                     |
| b. Only drugs that are highly lethal need   |  | arkoting materials                  |
| c. The effective dose is the dose that pro  |  | arketing materials.                 |
| d. A dose can be called effective only if t animals.                                    |  | defined effect in 75 percent of the |
| ANSWER: c   |  |                                     |
| 11. What percentage of the animals receiving a. 10 percent                              | g a drug must die in order for researc | hers to identify the lethal dose?   |
| b. 25 percent   |  |                                     |
| c. 50 percent   |  |                                     |
| d. 75 percent   |  |                                     |
| ANSWER: c   |  |                                     |
| 12. What is the lethal dose of Valium® in mic   | e?                                     |                                     |
| 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

| Name:  | Class:   | Date:               |
|--|--|---------------------|
| 02 Veterinary Drug Development and   | Control  |                     |
| <ul> <li>13. A dose can be called effective only if receive it.</li> <li>a. 10 percent</li> <li>b. 25 percent</li> <li>c. 50 percent</li> <li>d. 75 percent</li> </ul>                     | the amount of the test drug causes a defined effect in _   | of the animals that |
| ANSWER: c  |  |                     |
| 14. What value is determined by compara. Long-term toxicity b. Systems-oriented screen c. Chronic study d. Therapeutic index  ANSWER: d  | ing the drug's LD <sub>50</sub> and its ED <sub>50</sub> ? |                     |
| <ul><li>15. How long are tests conducted before</li><li>a. Three months</li><li>b. Six months</li><li>c. Three years</li><li>d. Six years</li></ul>  | they can be labeled non-carcinogenic?                      |                     |
| ANSWER: b  |  |                     |
| <ul> <li>16. What do systems-oriented screens te</li> <li>a. Toxicity</li> <li>b. Physiological systems</li> <li>c. Therapeutic indices</li> <li>d. Margins of safety</li> </ul> ANSWER: b | est?   |                     |
| 17. If there is a small difference between a. narrow therapeutic index b. broad therapeutic index c. narrow shelf life d. broad shelf life ANSWER: a                                       | an effective dose and a lethal dose then there is a        |                     |
| 18. A greater therapeutic index is represe<br>a. equal<br>b. larger<br>c. smaller<br>d. zero<br>ANSWER: b  | ented by a(n) number.                                      |                     |

|  | CLICK HERE TO                                   | ACCESS THE COMPLETE              | I Test Bank                 |
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| Name:  |   | Class:                           | Date:                       |
| 02 Veterinary Drug Dev   | velopment and Control                           | <u>I</u>                         |                             |
|  |   |                                  |                             |
| _  | · ·   | at is used as the measure of to  | xicity?                     |
| <ul><li>a. The effective dose</li><li>b. The lethal dose</li></ul> | <u> </u>  |                                  |                             |
| c. The margin of safe  | etv   |                                  |                             |
| d. Toxic evaluation  | ,   |                                  |                             |
| ANSWER: b  |   |                                  |                             |
| 20. What is monitored du   | uring therapeutic drug t                        | :herapy?                         |                             |
| 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> v                 | values are known for a g                        | given drug, how can you deter    | mine the therapeutic index? |
| a. By subtracting the  | LD <sub>50</sub> value by the ED <sub>50</sub>  | yalue                            |                             |
| $^{ m b.}$ By adding the LD $_{ m 5}$                              | $_{ m 0}$ value by the ED $_{ m 50}$ valu       | ıe                               |                             |
| c. By multiplying the  | LD <sub>50</sub> value by the ED <sub>50</sub>  | value                            |                             |
| $^{ m d.}$ By dividing the LD                                      | <sub>50</sub> value by the ED <sub>50</sub> val | lue                              |                             |
| ANSWER: d  |   |                                  |                             |
| 22. When researchers are   | e testing for fetal defect                      | ts, they are testing for which a | dverse effect?              |
| a. Carcinogenicity   |   |                                  |                             |
| b. Teratogenicity  |   |                                  |                             |
| c. Reproductivity  |   |                                  |                             |
| d. Toxicity  |   |                                  |                             |
| <i>ANSWFR</i> 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.

| Name:                                      | Class: | Date: |  |
|--|--------|-------|--|
| 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

| 1

#### 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. i 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. Teletriage
  - d. Teleconsulting

| 12. | A person studying how the body absorbs | uses, | and eliminates | codeine is eng | gaged in the |
|-----|--|-------|----------------|----------------|--------------|
|     | pharmacological specialty called       |       |                |                |              |

- a. pharmacotherapeutics
- b. pharmacodynamics
- c. pharmacokinetics
- d. pharmaconeurology

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|------|-------------|------------------|--|
| 71-2 | ( Antrollad | substances must  |  |
| LJ.  | COHLIGIEU   | annaranicea muar |  |

- 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 num | ber (e.g., V vs. | . I) of a controll | ed-substance drug, the |  |
|-----|-----------------------------|------------------|--------------------|------------------------|--|
|     |                             |                  |                    |                        |  |

| a. | higher | the | risk | for | human | abuse | potentia |  |
|----|--------|-----|------|-----|-------|-------|----------|--|
|----|--------|-----|------|-----|-------|-------|----------|--|

- 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 extralabel 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.

| <u> </u> | _  | _   |   |
|----------|----|-----|---|
| Chapter  | ٠, | ᄱ   | $\mathbf{V} \mathbf{I} \mathbf{\Delta} \mathbf{V} \mathbf{A}$ |
| CHADLLI  | _  | 11/ | V I C V V   |

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|    |    |   | •••   |        |

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.  $LD_{50}/ED_{50}$  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 longterm 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<sub>50</sub> /ED<sub>50</sub>). 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

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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.