

## Chapter 01: Introduction to Pharmacology, Drug Legislation, and Regulation

1. A historical timeline showing major pharmacological developments in a continuum may be divided into how many distinct periods?
- a. 3    b. 5
  - c. 6    d. 7

*ANSWER:* a

2. In the United States, the development of new drugs and drug therapies can take anywhere from:
- a. 2 to 3 years    b. 5 to 7 years
  - c. 7 to 15 years    d. 15 to 25 years

*ANSWER:* c

3. The age of natural substances is characterized by the use of which of the following?
- a. synthetic substances    b. DNA technology
  - c. biotechnology    d. plant derivatives

*ANSWER:* d

4. Which of the following is a branch of the United States Department of Health and Human Services?
- a. CDC    b. FDA
  - c. DEA    d. HHS

*ANSWER:* b

5. Pre-clinical investigation takes about:
- a. 1 to 3 years    b. 3 to 5 years
  - c. 5 to 7 years    d. 7 to 15 years

*ANSWER:* a

6. A new drug application for investigational human testing must be submitted to which of the following organizations?
- a. Department of Health    b. Drug Enforcement Agency
  - c. Federal Board of Pharmacy    d. Food and Drug Administration

*ANSWER:* d

7. Which of the following is the longest part of the drug approval process?
- a. pre-clinical investigation (stage 1)    b. clinical investigation (stage 2)
  - c. investigational new drug review (stage 3)    d. postmarketing studies (stage 4)

*ANSWER:* b

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8. A controlled substance is a medicinal product that has a high potential for abuse and is regulated by which of the following?
- a. FDA
  - b. DEA
  - c. CDC
  - d. DOH

*ANSWER:* b

9. Which of the following was the first attempt by the government to control and regulate the manufacture, distribution, and sale of drugs?
- a. The Harrison Narcotic Act
  - b. The Pure, Food, Drug, and Cosmetic Act
  - c. The Pure Food and Drug Act
  - d. The Comprehensive Drug Abuse Prevention and Control Act

*ANSWER:* c

10. The Comprehensive Drug Abuse Prevention and Control Act is also called the:
- a. Narcotic Substances Act
  - b. Non-narcotic Substances Act
  - c. Food, Drug, and Cosmetic Act
  - d. Controlled Substances Act

*ANSWER:* d

11. Which of the following drug schedules has the least potential for abuse?
- a. Schedule II
  - b. Schedule III
  - c. Schedule IV
  - d. Schedule V

*ANSWER:* d

12. Which of the following drug schedules does not require a prescription?
- a. Schedule IV
  - b. Schedule V
  - c. Schedule III
  - d. Schedule II

*ANSWER:* b

13. Tylenol with codeine is an example of which drug schedule?
- a. Schedule I
  - b. Schedule II
  - c. Schedule III
  - d. Schedule IV

*ANSWER:* c

14. Cough syrups with codeine are examples of which drug schedule?
- a. Schedule IV
  - b. Schedule V
  - c. Schedule III
  - d. Schedule I

*ANSWER:* b

## Chapter 01: Introduction to Pharmacology, Drug Legislation, and Regulation

15. Methadone is an example of which drug schedule?

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

*ANSWER:* b

16. Which of the following drug schedules may permit 5 refills in 6 months?

- a. Schedules I and V    b. Schedules II and V
- c. Schedules I and II    d. Schedules III and IV

*ANSWER:* d

17. One of the earliest written records of medicinal uses of plants was found in:

- a. Greece      b. Egypt
- c. Italy        d. England

*ANSWER:* b

18. The use of proteins from cells and tissues of humans, animals, and plants in order to produce medicines and therapeutic treatments is called:

- a. pharmacology    b. synthetic medicine
- c. biochemistry    d. biotechnology

*ANSWER:* d

19. Stage 3 of drug product development is known as:

- a. investigational new drug review    b. postmarketing studies
- c. pre-clinical investigation          d. clinical investigation

*ANSWER:* a

20. Which of the following organizations or agencies is able to remove a drug from the market when the drug is found to cause serious problems?

- a. DEA      b. CDC
- c. FDA      d. state board of pharmacy

*ANSWER:* c

21. A prescription drug is known as a \_\_\_\_\_ drug.

*ANSWER:* legend

22. The study of the sources, appearance, chemistry, actions, and indications of drugs is called \_\_\_\_\_.

*ANSWER:* pharmacology

23. Antibiotics and insulin are examples of \_\_\_\_\_ substances.

*ANSWER:* synthetic

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

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24. The Food and Drug Administration is a branch of the United States Department of \_\_\_\_\_.

*ANSWER:* Health and Human Services  
HHS

25. Clinical testing on humans takes place in three different phases, called clinical \_\_\_\_\_.

*ANSWER:* phase trials  
trials

26. Investigational New Drug (IND) Review is the \_\_\_\_\_ stage of drug approval.

*ANSWER:* third

27. OTC drugs do not require a \_\_\_\_\_.

*ANSWER:* prescription

28. The DEA is a part of the United States Department of \_\_\_\_\_.

*ANSWER:* Justice

29. Before the Harrison Narcotic Act, any narcotic could be purchased \_\_\_\_\_.

*ANSWER:* without a prescription

30. Drugs in Schedule I have the highest potential for \_\_\_\_\_ and \_\_\_\_\_.

*ANSWER:* abuse, addiction  
addiction, abuse

31. The period from 1350 to 1650 A.D. (the later stages of the Middle Ages) is known as the \_\_\_\_\_.

*ANSWER:* renaissance

32. In the United States, the development of new drugs can take anywhere from seven to \_\_\_\_\_ years.

*ANSWER:* fifteen

33. Most prescription drugs are designated by the \_\_\_\_\_.

*ANSWER:* FDA

34. The Harrison Narcotic Act regulated the importation, manufacture, sale, and use of opium, \_\_\_\_\_, and their derivations.

*ANSWER:* codeine

35. The Kefauver-Harris Amendment of 1963 required that prescription and non-prescription drug products be \_\_\_\_\_, \_\_\_\_\_, and safe.

*ANSWER:* pure; effective

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

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36. Under OBRA-90, pharmacists in every state must offer to \_\_\_\_\_ all patients and review medications that they are taking.

*ANSWER:* counsel

37. The three sections of HIPAA include privacy and security regulations, as well as \_\_\_\_\_ standards.

*ANSWER:* transaction

38. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is also known as the \_\_\_\_\_ Modernization Act.

*ANSWER:* Medicare

39. OBRA-90 was designed to save patients \_\_\_\_\_, and expanded on OBRA-97.

*ANSWER:* money

40. \_\_\_\_\_ drugs have the least potential for abuse.

*ANSWER:* Schedule V