

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

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

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: _____

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

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: _____

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

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