

7. Marker selection has to be done by the use of following except
 - a. Herbal monographs
 - b. Experience, transfer from other plants/constituents.
 - c. Literature research about known constituents.
 - d. Random selection
8. Which of the following tests are not necessary for herbal substance/herbal preparations
 - a. Accelerated stability testing
 - b. Stress testing
 - c. Intermediate stability testing
 - d. Toxicity testing
9. The world medical Association, declaration of Helsinki provides the following
 - a. Recommendation guiding physicians in biomedical research involving human subjects
 - b. Recommendation guiding physicians on dosage forms
 - c. Recommendation guiding pharmacist on drug interactions and safety indications
 - d. Recommendation guiding pharmacist on quality control of drugs
10. ----- describes the Good Manufacturing Practice for Ayurvedic, Siddha and Unani Medicines.
 - a. Schedule Z
 - b. Schedule T
 - c. Schedule M
 - d. Schedule Y
11. A Churna formulation contains Senna, Rhubarb and Aloe. The chemical test used to identify the phytoconstituents is
 - a. Borntrager test
 - b. Vanillin in sulphuric acid test
 - c. Mayers test
 - d. Legal test.
12. Constituents or groups of constituents which are generally accepted to contribute to the therapeutic activity.
 - a. Active marker
 - b. Analytical marker
 - c. Negative marker
 - d. Non clinical marker
13. In Indian pharmacopoeia a monograph of herbal drugs includes following details are except
 - a. Chemical constituents
 - b. Reference standards
 - c. Identification test
 - d. Drug Interaction

14. ICH Q2 (R1) refers to
 - a. Stress testing of crude drugs
 - b. Validation of analytical procedures
 - c. Stability testing of crude drugs
 - d. Impurity testing

15. The observation in acute toxicity studies is conducted for
 - a. 24 hours
 - b. 7-14 days
 - c. 30 days
 - d. 60-90 days

16. Stress testing is done to
 - a. To determine stability
 - b. To determine shelf life
 - c. To Determine the degradation pathway
 - d. To determine the purity of drugs

17. According to WHO, Herbal preparations include all except
 - a. Extracts
 - b. Tinctures
 - c. Crude drug powder
 - d. Essential oils

18. Skin irritation test on animals is conducted by
 - a. Draizes test
 - b. Ames test
 - c. LAL test
 - d. Goldbeaters test

19. Lycopene gets converted from trans form to cis form during storage. This process is called _____
 - a. Polymerisation
 - b. Geometric isomerisation
 - c. Racemisation
 - d. Oxidation

20. A request to return a product after the manufacturer finds defect is called _____ a product
 - a. Recall
 - b. Reprocess
 - c. Rework
 - d. Recover

Q.2 Attempt any two questions out of three

20M

1. Discuss the guidelines for evaluating the safety and efficacy of herbal medicines
2. a. Explain any one drug monograph according to Indian Pharmacopoeia
b. Explain in brief about good collection practices of herbal drugs
3. a. Explain the basic tests for medicinal plants materials as per WHO
b. Discuss the preparation of documents for new drug application and export registration of herbal drugs

Q.3. Attempt any seven questions

35M

1. Enlist the physicochemical tests for the quality evaluation of herbal drugs and describe any two.
2. Write a short note on chromatography in the standardisation of crude drugs
3. Discuss EU guidelines for quality control of drugs.
4. Explain the importance of determination of pesticide residue and heavy metal analysis in herbal drugs
5. Describe importance of GLP in the Herbal Industry
6. What are the best practices in the cultivation of herbal raw material as per GACP?
7. Describe the regulatory requirements of herbal drugs
8. Explain the stability testing of herbal drugs
9. Define and classify markers. Describe the role of markers in standardization of herbal products.
