2024/05

SET A

B. PHARM.
EIGHTH SEMESTER
QUALITY CONTROL & STANDARDIZATION OF HERBALS
BP806ET

[USE OMR SHEET FOR OBJECTIVE PART]

Duration : 3 hrs. **Full Marks : 75**

(PART-A: Objective)

Time : 30 min. **Marks : 20**

Choose the correct answer from the following: ***1×20=20***

1. Ketamine hydrochloride is a..... crystalline powder
   a. Brown
   b. White
   c. Cream
   d. None of the above
2. Ruthenium red test is used to detect.....
   a. Tannins
   b. Gums and mucilage
   c. Resins
   d. Fixed oils and Fats
3. Fresh herbal materials should be stored between.....
   a. 0°C to 8°C
   b. 2°C to 8°C
   c. 2°C to 15°C
   d. 10°C to 15°C
4. GACP stands for
   a. Good agriculture and collection procedures
   b. Good agriculture and collection practices
   c. Good agriculture and cultivation practices
   d. None of these
5. 'SOP' stands for
   a. Standard Operating personnel
   b. Standard Operating procedure
   c. Standard Operating practices
   d. Standard Operating professionals
6. Magnesium sulfate is a..... crystal
   a. Pale brown
   b. Light green
   c. Cream
   d. Colourless
7. SOP written to explain the procedures of
   a. Cleaning
   b. Testing
   c. Routine inspection
   d. All of the above
8. In cGMP 'c' stands for
   a. Control
   b. Common
   c. Continue
   d. Current
9. Quarantine means.....
   a. Storage of documents
   b. Storage of reference items
   c. Storage of herbal materials
   d. Storage of finished goods

10. Disposal of waste in herbal drug industry should be as per the guidelines of
    a. Industry norms
    b. WHO guidelines
    c. OECD guidelines
    d. Pollution Control Board

11. What is the full form of ICH?
    a. International Council for Harmonization of Technical Requirements for Pharmaceutical for human use
    b. International Council for Harmonization of Technical Regulatories for Pharmaceuticals for human use.
    c. Both a & b
    d. None of the above

12. What is the full form of GCMS?
    a. Gas Chromatography Mass Spectrometry
    b. Gas Liquid Chromatography Mass Spectrometry
    c. Gas Chromatography& Mass Spectrometry
    d. All of the above

13. ICH 2nd category deals with
    a. Safety
    b. Impurities
    c. Analytical Validation
    d. All of the above

14. Which of following is a toxicity study-
    a. Acute toxicity
    b. Non acute toxicity
    c. Non chronic toxicity
    d. All of the above

15. How many animal species are required to perform long term toxicity test?
    a. 2
    b. 3
    c. 4
    d. 5

16. What is the full form of CDSCO?
    a. Central Drugs Standards Control Organization
    b. Current Drugs Standards Control Organization
    c. Clinical Drugs Standards Control Organization
    d. Checking Drugs Standards Control Organization

17. GMP comes in which schedule of Drugs and Cosmetic act 1940?
    a. Schedule M
    b. Schedule Y
    c. Schedule A
    d. Schedule R

18. What is POCA cycle?
    a. Plan-Do-Check-Act
    b. Plan-Did-Control-Act
    c. Plan-Do-Control-Act
    d. Plan-Did-Check-Act

19. ASU is under the purview of-
    a. AYUSH
    b. FDA
    c. CDSCO
    d. NDA

20. Animal studies, clinical trials, extraction/isolation studies are part of which application process?
    a. NDA
    b. GMP
    c. IND
    d. FDA

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PART-B :Descriptive

Time : 2 hrs. 30 min. **Marks : 35**

[Answer any seven (7) questions]

1.	Explain the six system inspection model.	5
2.	Write WHO guidelines for quality control of herbal drugs?	5
3.	Write the test procedure for three pharmaceutical substances.	5
4.	Define Herbal Pharmacopoeia? Write a brief note on British Herbal Pharmacopoeia?	1+4=5
5.	Write the name of the parties involved in ICH?	5
6.	Write the quality specifications of herbal medicines in terms of information for medicinal preparation of plant material	5
7.	Define marker compounds? Write 4 roles of markers in the standardization of herbal products?	1+4=5
8.	Describe five building and facilities under GMP?	5
9.	Define quality assurance? Write five objectives of auditing?	1+4=5

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PART-C: Long type questions

[Answer any two (2) questions]

1. Describe the acute toxicity guidelines for investigation of herbal medicines? **10**

2. Explain WHO guidelines on cGMP for herbal medicines? **10**

3. Describe the guidelines for the export of drugs issued by Ministry of Health and Family Welfare? **10**

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