SET B

B. PHARM.
EIGHT SEMESTER
QUALITY CONTROL & STANDARDIZATION OF HERBALS
BP806ET [SPECIAL REPEAT]

[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. What is the full form of ICH?
   a. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
   b. Both 'a' & 'c'
   c. Indian Council for Harmonisation of Technical Regulatories for Pharmaceuticals for Human Use
   d. None of the above

2. What is the full form of HPLC?
   a. High Performance Level Chromatography
   b. High Performance Liquid Chromatography
   c. High Performance Layer Chromatography
   d. High Ultra Performance Level Chromatography

3. Pharmacodynamics is.....
   a. Study of Drug's biochemical, therapeutic effect on the body.
   b. Study of a Drug's Toxicity effect only
   c. Study of Body's physiological effects on the drug.
   d. All of the above

4. Pharmacokinetics is.....
   a. Study of Body's physiological effects on the drug.
   b. Study of a Drug's Toxicity effect only
   c. Study of Drug's biochemical, therapeutic effect on the body.
   d. None of the above

5. Which of the following is a Toxicity Study?
   a. Chronic Toxicity Study
   b. Sub-Chronic Toxicity Study
   c. Acute Toxicity Study
   d. All of the above

6. ICH Q2 Guideline deals with.....
   a. Stability
   b. Impurities
   c. Analytical Validation
   d. None of the above

7. Full form of NMR is....
   a. Nuclear Magnetic Resonance
   b. Nuclear Ultra Magnetic Resonance
   c. Novel Magnetic Resonance
   d. Nuclear Mass Resonance

8. ICH Q1A- Q1F Guideline deals with.....
   a. Stability Studies of New Drug Substances
   b. Self-Inspection
   c. Analytical Validation
   d. All of the above

9. Full form of UV Spectrophotometer is....
   a. Ultraviolet Spectrophotometer
   b. Both 'a' and 'c'
   c. Ultraviolet and Mass Spectrophotometer
   d. None of the above

10. Isocratic elution is....
   a. Consistent and Single Mobile Phase
   b. Both 'a' and 'c'
   c. Ranges of Mobile Phases in a mixture
   d. None of the above

11. Gradient elution is....
   a. Ranges of Mobile Phases in a mixture
   b. Both 'a' and 'c'
   c. Consistent and Single Mobile Phase
   d. None of the above

12. Silica Gel of which grade is applicable for Column Chromatography?
   a. Silica Gel 60 grade
   b. Silica Gel G grade
   c. Silica Gel 260 grade
   d. All of the above

13. Successive solvent extraction is....
   a. Solvent free extraction
   b. Selecting any solvent
   c. Towards a polar solvent from a non polar solvent
   d. Isolation of compounds

14. The main class of chemical for Senna leaf is?
   a. Glycosides
   b. Sterols
   c. Resins
   d. Tannins

15. Which dosage form is prescribed for Hypocalcemia tetany?
   a. Calcium gluconate
   b. Streptozotocin
   c. Captopril
   d. Alloxan

16. Doxorubicin Hydrochloride injection is used for?
   a. Cancer
   b. SARS
   c. Asthma
   d. COPD

17. What is the full form of cGMP?
   a. Current Good Manufacturing Practices
   b. Critical Good Manufacturing Practices
   c. Good Manufacturing Practices
   d. Curative Good Manufacturing Practices

18. Minimum requirements for herbal drug manufacturing and quality control is under which Schedule?
   a. Schedule H
   b. Schedule M
   c. Schedule T
   d. Schedule C

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

20. What is the full form of HPTLC?
   a. High Performance Thick Layer Chromatography
   b. High Performance Thick Liquid Chromatography
   c. High Performance Thin Layer Chromatography
   d. All of the above

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PART-B :Descriptive

Time : 2 hrs. 30 min. Marks : 35

[Answer any seven (7) questions]

1. Explain the Thin Layer Chromatography and Column Chromatography Techniques? 5

2. Describe the Physical evaluation methods of Herbal Drugs? 2+1.5+1.5=5

3. Explain the Criteria for Documentation of New Drug Application. 5

4. Define the following: Herbs, Herbal medicines, Active ingredients, Markers and Therapeutic activity. 5

5. Explain the EU Guidelines for quality control of herbal drugs. 2.5+2.5=5

6. Explain the ICH Guidelines for quality control of herbal drugs. 5

7. Explain the Regulatory requirements for herbal medicines. 1+1+1+ 1+1=5

8. Explain the Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines. 5

9. Describe the Macroscopical, Microscopical evaluation techniques of Herbal Drugs. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Describe the basic pharmaceutical tests for any five Dosage Forms? 10

2. Define Stability test and Explain the different parameters for Drug stability testing. 2.5+2.5+ 2.5+2.5 =10

3. Explain the Role of Chemical and Biological markers in standardization of herbal products. 10

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