Roll No. Total No. of Pages: 02

Total No. of Questions: 13

B.Pharmacy (Sem.-8)

QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Subject Code: BP806ET M.Code: 79769

Date of Examination: 09-01-2023

Time: 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES:

- 1. SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.
- 2. SECTION-B contains THREE questions carrying TEN marks each and student has to attempt any TWO questions.
- 3. SECTION-C contains NINE questions carrying FIVE marks each and student has to attempt any SEVEN questions.

SECTION-A

1. Write briefly:

- a) Give the full form of GACP and GMP.
- b) What are markers?
- c) What are crude drug and herbal products?
- d) According to you, what are the 3 fundamental requirements for herbal drugs?
- e) What is microscopic evaluation of plant drugs?
- f) What is phytochemical screening?
- g) Give the sequence of instrumentation in HPLC.
- h) Name two detectors used in gas chromatography.
- i) What are different ICH guidelines?
- j) Give the conditions for accelerated stability testing of herbal formulations.

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SECTION-B

- 2. Discuss the need and steps for evaluating quality, efficacy and safety of herbal drugs.
- 3. "Chromatographic techniques play an important role in the study of plant drugs". Justify this statement with appropriate examples.
- 4. Discuss the research guidelines for evaluating efficacy and safety of traditional herbal medicines and phytoconstituents.

SECTION-C

- 5. Compare TLC and HPTLC.
- 6. What is the process and importance of GACP of medicinal plants?
- 7. Compare the requirements for herbal drugs as per IP and WHO.
- 8. What is pharma-covigilance of herbal drugs?
- 9. What are the regulatory requirements for herbal drugs and products in India?
- 10. Describe the process for stability testing of herbal products.
- 11. What are the requirements for new drug development and registration?
- 12. Write a note on steps involved in plant drug standardization.
- 13. What are the GMP requirements for herbal products?

NOTE: Disclosure of Identity by writing Mobile No. or Marking of passing request on any paper of Answer Sheet will lead to UMC against the Student.

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