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Total No. of printed pages = 02

Monsoon, 2023
M.Pharm Semester Examinations
Industrial Pharmacognostical Technology
Course Code: MPG104T

Full Marks – 75

Time – 03 hours

The figure in the margin indicates full marks for the questions.

- 1. Answer the following questions:** (not more than 100 words) (10 × 2 = 20)
- a. What is Patentable subject matter with regards to herbal drugs?
 - b. Enlist the parameters of herbal drugs for monograph preparation according to IP.
 - c. Define TQM.
 - d. Enumerate the importance of TRIPS with regards to protection of intellectual rights on pharmaceuticals.
 - e. Enlist the amendments to Indian Patent laws with respect to herbal products and processes.
 - f. Describe the significance of double blind study in clinical study design.
 - g. Define ISO-9000.
 - h. Define the term Capital Venture with regards to setting up an herbal drug industry.
 - i. Write a short note on British Herbal Pharmacopoeia.
 - j. In which year Indian Patents Act was passed? When the third amendment to the Indian Patents Act came into force?
- 2. Short answers (Answer any seven):** (not more than 500 words) (7 × 5 = 35)
- a. Elaborate on the Procedure for Indian patent filing.
 - b. Describe the different stages of clinical trial with significance of each stage.
 - c. Prepare a note on quality assurance of herbal drugs.
 - d. Write a short note on Entrepreneurship development in herbal drugs.
 - e. Differentiate between the monographical protocol of American Herbal Pharmacopoeia and Ayurvedic Pharmacopoeia.

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f. Describe the application of GLP in drug discovery from natural sources.

g. Define the following

(i) Geographical indication

(ii) Novelty of Patents

h. Briefly describe the importance of Global marketing management of herbal drugs.

i. Briefly describe the process of establishing an herbal drug industry in India.

3. Long answers (Answer any two): (not more than 1000 words)

(2 × 10 = 20)

a. Prepare a note on WHO guidelines in quality assessment of herbal drugs.

b. Prepare a note on stability study of herbal drugs by application of different protocols.

c. Enumerate the important points for application of GMP in herbal drugs manufacturing.