

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0823]

**AUGUST 2023
(MARCH 2023 EXAM SESSION)**

Sub. Code: 2082

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS**

Q.P. Code: 562082

Time: Three hours

Maximum: 75 Marks

I. Elaborate on: Answer any TWO questions. (2 X 10 = 20)

1. Describe chromatography techniques in the standardization of herbal drugs.
2. What do you understand by quality assurance in herbal industry? Explain the importance of GMP in herbal industry.
3. Write about European medicine agency (EMA). Enumerate the European guidelines on quality of herbal medicinal product.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Define and classify markers with examples.
2. Explain the procedure and significance on microscopical evaluation of herbal drugs.
3. Enlist the document required for export registration.
4. Write note on ICH guidelines.
5. Give the clinical guidelines on assessment of safety and efficacy of herbal medicine.
6. Write a note on good practice for harvesting and storage of herbal products.
7. What is traditional system of medicine? What are the GLP requirements in traditional system of medicine?
8. Explain the protocol for stability testing of herbal medicines.
9. What are the basic test for alkaloids and glycosides in herbal products?

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. What are pesticides? Give two examples.
2. Define processed and finished herb as per WHO.
3. Swelling factor and its significance.
4. Components of HPLC.
5. Define TLC and HPTLC.
6. Authentication of medicinal plants.
7. Importance of ash values.
8. List out any four Pharmacopoeia.
9. Examples of herbal drug interaction.
10. Define shelf life.
