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BP 806ET

2025

B.Pharm. 8th Semester (Regular) End-Term Examination

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (THEORY)

Full Marks – 75 Time – Three hours

The figures in the margin indicate full marks for the questions.

PART – A (Multiple choice questions)

1. Choose the correct answer from the following: 1×20

(i) Which of the following plant bioactive molecules is specified in the WHO basis tot of pharmaceutical substances?

(a) Ephedrine hydrochloride

(b) Vinblastine sulphate

(c) Atropine sulphate

(d) Emetine hydrochloride

(ii) Which of the following test is used for the identification of flavonoids?

(a) Baljet test (b) Salkowski test

(c) Shinoda test (d) None of the above

(iii) Foaming index test indicate ————

(a) Presence of carbohydrates

(b) Presence of steroidal saponin

(c) Presence of flavonoid glycoside

(d) Presence of alkaloid

(iv) Swelling index test indicate ————

(a) Presence of mucilage

(b) Presence of protein

(c) Presence of pungent principles

(d) Presence of calcium oxalates

[Turn over

(v) Which of the following apparatus is used to measure the density of a liquid substance?

(a) Pycnometer

(b) Clevenger apparatus

(c) Karl Fisher apparatus

(d) Soxhlet apparatus

(vi) As per WHO guidelines the loss on drying (gravimetric method) of plant material is performed in an over at ———— temperature.

(a) 90-95°C (b) 95-100°C

(c) 100-105°C (d) Above 120°C

(vii) GACP stands for ————

(a) Good Agricultural and Collection Procedures

(b) Good Agricultural and Collection Practices

(c) Good Agricultural and Cultivation Practices

(d) Good Agricultural and Cultivation Procedures

(viii) Components of GAP include which of the following options?

(a) Plant species identification and authentication

(b) Training of personnel and personal hygiene

(c) Encourage and support the sustainable cultivation and collection

(d) All of the above

(ix) Manufacturing area for the production of sterile Ayurvedic products should be ————

(a) Bacteria Free (b) Dust Free

(c) Moisture Free (d) All of the above

(x) As per OECD guidelines, the acute toxicity studies is conducted for a period of ———— days

(a) Up to 14 days (b) Up to 30 days

(c) Up to 60 days (d) Up to 100 days

(xi) Under EU Directive 2004/24/EC, traditional products that do not require regulation by the EU must provide evidence of long-standing use for atleast how many years?

(a) 5 years (b) 10 years

(c) 15 years (d) 30 years

(xii) 'Standard operating procedures' are guidelines which explains ————

(a) Systematic procedures for testing

(b) Systematic procedures for manufacturing

(c) Systematic procedures for quality assurance

(d) All of the above

(xiii) Under WHO guidelines for the assessment of herbal medicine safety, which category includes 'herbal medicine of uncertain safety'?

(a) Category-I (b) Category-II

(c) Category-III (d) Category-IV

(xiv) Which application form is used for obtaining permission to import or manufacture a new drug?

(a) Form 44 (b) Form 45

(c) Form 46 (d) Form 47

(xv) In India, which of the following national regulating authority is responsible for approving new drugs, conducting clinical trials, setting standard and quality control of imported drugs?

(a) The Food Safety and Standards Authority of India (FSSAI)

(b) Central Drugs Standard Control Organization (CDSCO)

(c) The Pharmacy Council of India (PCI)

(d) All of the above

(xvi) Which of the following chemical markers of Rauwolfia exhibit antihypertensive effects?

(a) Resveratrol (b) Rosmainic acid

(c) Reserpine (d) Retinol

(xvii) Gel permeation chromatographic techniques is used to separate _____

(a) DNA and RNA

(b) Metals

(c) Inorganic substances

(d) None of the above

(xviii) Under which rule is a 'No Objection Certificate for the export of drugs from India' issued by the Ministry of Health and Family Welfare for export purposes?

(a) Rule 64 (b) Rule 74

(c) Rule 84 (d) Rule 94

(xix) Which of the following criteria is true for conducting accelerated stability testing of herbal drugs?

(a) 25°C ±2°C, RH± 5% for 6 months

(b) 30°C ±°C, RH± 5% for 6 months

(c) 40°C ±2°C, RH± 5% for 6 months

(d) 50°C ±2°C, RH ± 5% for 6 months

(xx) Which of the following statements about the 'shelf life of a drug' is true?

(a) The time required for a drug to reach its maximum potency

(b) The period during which a drug retains its expected potency, safety, and efficacy when stored under recommended conditions

(c) The time it takes for a drug to be completely eliminated from the body

(d) The duration for which a drug remains effective after opening the container

PART — B

2. Answer the following questions (any SEVEN): 7 × 5

(a) Formulate and appraise the basic testing procedures for vinblastine sulphate. 5

(b) Explain in detail *anyone* of the following guidelines for quality control of herbal drugs. 5

(i) European Union guidelines

(ii) ICH guidelines

(c) Write a short note on *any one* of the following : 5

(i) cGMP in traditional system of medicine

(ii) GAP in traditional system of medicine

(d) Discuss in detail the 'AMES test' and its significance. 5

(e) Give the application of chromatographic techniques 'HPTLC and GC-MS' incorporated in the standardization of herbal products. 5

(f) Explain GLP in the traditional system of medicine. 5

(g) Discuss the role of chemical and biological markers in standardization of herbal products.

(h) Describe the role of pharmacovigilance system in monitoring of herbal medicine. 5

(i) Discuss in detail the regulatory requirement for herbal medicine. 5

PART — C

Answer the following questions (any TWO): 2 × 10

3. (a) Summarize the various standardization parameters prescribed as per WHO guidelines for herbal drugs and describe in detail the evaluation methods of Swelling index and foaming index. 4 + 3+ 3

(b) Enumerate the different research guidelines incorporated for evaluating safety/toxicity of herbal medicine and describe anyone in detail. 3 + 7

(c) Explain the different stages/guidelines required for preparation of documents for NDA approval process in India. 10