Total No. of printed pages = 4

17/5/24

BP 806 ET

Roll No. of candidate | | | | | | | | | | |

2024

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

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (THEORY)

New Regulation (w.e.f. 2017-2018)

Full Marks – 75 Time – Three hours

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

PART – A

1. Answer the following (MCQ/ Fill in the blanks) : (20 × 1 = 20)

(i) Which of the following dye is used in the basic test for fixed oil and fats?

(a) Ruthenium red (b) Indigo blue

(c) Methyl orange (d) None of the above

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

(a) Benedict test (b) Baljet test

(c) Salkowski test (d) Shinoda test

(iii) In cGMP the letter 'c' stands for _____

(a) Current (b) Control

(c) Common (d) Centre

(iv) The optimal storage condition for fresh Herbal material is _____

(a) 0°C to 8°C (b) 2°C to 8°C

(c) 2°C to 15°C (d) 10°C to 15°C

(v) Disposal of waste in herbal drug industry should be as per the guidelines of _____

(a) ICR guidelines (b) WHO guidelines

(c) OECD guidelines (d) Pollution Control Board

[Turn over

(vi) EMA stands for which of the following options?

(a) European Medicine Agency

(b) European Medicine Authority

(c) European Medicine Activity

(d) European Medicine Association

(vii) As per WHO guidelines, the acute toxicity studies is conducted for a period of _____ days

(a) Up to 14 days (b) Up to 2 months

(c) Up to 6 months (d) None of the above

(viii) Which schedule of the Drug and Cosmetic Act (1940) lays down the GMP requirements to be followed for the manufacturing of herbal medicine'?

(a) Schedule Y (b) Schedule M

(c) Schedule T (d) Schedule X

(ix) A new active medicinal ingredient that requires EU regulations falls under which directive?

(a) 2001/83/EC (b) 2002/83/EC

(c) 2004/24/EC (d) None of the above

(x) The full form of EFSA is _____

(a) European Food Safety Association

(b) European Food Safety Authority

(c) European Food Safety Agency

(d) None of the above

(xi) 'Herbal medicine of uncertain safety' falls under which category of WHO guidelines for assessment for safety of herbal medicines?

(a) Category – I (b) Category – II

(c) Category – III (d) Category – IV

(xii) Which of the following OECD guidelines is applicable for testing acute oral toxicity based on a 'Fixed dose procedure' in animals?

(a) OECD guideline no. 420 (b) OECD guideline no. 423

(c) OECD guideline no. 425 (d) OECD guideline no. 434

(xiii) Which of the following form is applied for the 'Issue of permission to import or manufacture a new drug'?

(a) Form 41 (b) Form 42

(c) Form 43 (d) Form 44

(xiv) Components of GMP include which of the following options?

(a) Design and construction of the industry

(b) Quality control

(c) Training of personnel's

(d) All of the above

(xv) Under which rule a 'No Objection Certificate for export of drugs from India' is applied to be issued by the Ministry of Health and Family Welfare for export purpose?

(a) Rule 94 (b) Rule 95

(c) Rule 96 (d) Rule 97

(xvi) In India, who among the following issued the authority to a pharmaceutical company who wish to manufacture/import a new drug?

(a) Pharmacy Council of India

(b) Medical Council of India

(c) Director General of Health Services

(d) Drugs Controller General of India

(xvii) Which of the following is true for a Chemical marker of medicinal plants?

(a) Chemical marker are pure herbal extract

(b) Chemical marker are pure and mixture of constituents

(c) Chemical marker are pure and single constituents

(d) None of the above

(xviii) The 9th Edition of Indian Pharmacopoeia was published in which year?

(a) 2020 (b) 2021

(c) 2022 (d) 2023

(xix) 'Pharmacovigilance' or 'safety surveillance' is involved in which of the following Clinical trials?

(a) Phase – I (b) Phase – II

(c) Phase – III (d) Phase – IV

(xx) What is the full abbreviated form of 'ICH'?

(a) Internal Central for Harmonization

(b) International Council for Harmonization

(c) Indian Council for Harmonization

(d) None of the above

PART – B

Answer the following questions (any *seven*) : (7 × 5 = 35)

2. (a) Discuss in detail the basic testing procedures for drugs giving special emphasis to medicinal plants. (5)

   (b) Discuss a brief note on any one of the following : (5)

   (i) cGMP

   (ii) GACP.

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

   (d) Explain the different chromatographic techniques incorporated in the standardization of herbal products. (5)

   (e) Discuss the detail process for preparation of documents for NDA and export registration. (5)

   (f) Discuss the role of chemical markers in standardization of herbal products. (5)

   (g) Give a detail comparison on various herbal pharmacopoeias. (5)

   (h) Discuss in detail the OECD guidelines for toxicity testing of drugs. (5)

   (i) Outline the objectives on WHO basic test for pharmaceutical substances and describe the identity test of viublastine sulphate. (2+3)

PART – C

3. Answer the following questions (any *two*) : (2 × 10 = 20)

   (a) Discuss in details the EU and ICH guidelines for quality control of herbal drugs. (10)

   (b) Categorize the various standardization parameters prescribed as per WHO guidelines for herbal drugs and describe in detail the assessment methods of ash values and foaming index. (4+3+3)

   (c) Examine and discuss in detail the following guidelines *(any one)* : (10)

   (i) WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.

   (ii) WHO Guidelines on GACP for Medicinal Plants.