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2023

B.Pharm. 8th Semester End-Term Examination

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (THEORY)

(New Regulation w.e.f. 2017-18)

Full Marks – 75 Time – Three hours

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

1. Answer all questions : (20)

(A) Multiple choice questions : (10 × 1 = 10)

(i) Gentamycin injection is a sterile solution usually containing ———— of Gentamicin

(a) 10-40 mg (b) 100-400 mg

(c) 20-40 mg (d) None of the above

(ii) Frozen herbal material should be stored below

(a) –10°C (b) –18°C

(c) 0° C (d) None of these

(iii) Quality assurance of herbal medicinal products is the responsibility of

(a) Manufacture (b) Regulatory bodies

(c) Both (a) and (b) (d) NOA

(iv) Astringent property is determined by amount of ———— present in the drug

(a) Tannin (b) Saponin

(c) Glycoside (d) None of above

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(v) Average number of stomata present per ———— of the epidermis is known as stomatal number

(a) Sq. mm (b) Sq. cm

(c) Sq. μm (d) None of these

(vi) A new active medicinal ingredients that require regulations falls under which directive

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

(c) Directive 2004/24/EC (d) None of these

(vii) Good Manufacturing Practices in Drugs and cosmetics Act 1940 and rules 1945 comes under ————

(a) Schedule T (b) Schedule M

(c) Schedule C (d) Schedule V

(viii) Which of the following is a common analytical technique used for standardization of herbal medicines?

(a) HPTLC (b) HPLC

(c) GC (d) All of the above

(ix) Which of the following OECD guidelines is applied for acute oral toxicity study for herbal medicine?

(a) OECD 402 (b) OECD 410

(c) OCED 420 (d) OECD 434

(x) What is the full form of CDSCO?

(a) Central Drug Standard Control Organization

(b) Council for Drug Standard Control Organization

(c) Central Drug Systematic Control Organization

(d) None of the above

(B) Fill up the blanks : $(10 \times 1 = 10)$

(i) Generally ———— ethyl alcohol is used for determination of alcohol soluble extractive value.

(ii) Department of ———— is the regulatory authority and mandate that any manufacture or marketing of herbal drugs have to be done after obtaining manufacturing license.

(iii) Amikacin sulfate is a ———— powder.

(iv) The moisture content is determined by heating a drug at ———— in an oven to a constant weight.

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(v) Unani system of medicine has its root in ————.

(vi) Form number ———— is required for the issue of permission to import or manufacture of a new drug.

(vii) Components of GMP includes ————

(viii) EMA stands for ————

(ix) TTC stands for ————

(x) ———— is the only authorized apex body to grant permission to manufacture/import of new drug in India.

2. Answer any *seven* from the following (7 × 5 = 35)

(a) Enlist Ayurvedic drug manufacturing license approval steps. (5)

(b) Give objectives for basic test of drugs. (5)

(c) Write a note on guidelines for stability testing of herbal medicine. (5)

(d) Write a note on chemical and biological markers in standardization of herbal products. (5)

(e) Explain GACP on herbal medicinal plants. (5)

(f) Differentiate between TLC and HPTLC. Give two tests for identification of Tannin. (2+3)

(g) Define OECD guidelines. Describe the OECD guidelines for evaluating the safety and efficacy of herbal medicines. (1+4)

(h) Describe in details the process for the preparation of document for new drug application (NDA). (5)

(i) Write a note on challenges in monitoring the safety of herbal medicine. (3+2)

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

(a) What is Pharmacovigilance? Enumerate WHO guidelines on safety monitoring of herbal medicine in Pharmacovigilance system. (2+8)

(b) Explain in detail about the WHO guidelines of quality control of herbal drugs. (10)

(c) Write a note on anyone of the following. (10)

(i) European Union regulatory guidelines for quality control of herbal medicine

(ii) ICH guidelines for quality control of herbal medicine.

————