Total No. of printed pages = 6

BP 806 ET

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

28/08/22

2022

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. Multiple choice questions : (20 × 1 = 20)

(i) ICH stands for?

(a) Indian council for harmonization

(b) International conference for harmonization

(c) International council for harmonization

(d) Indian conference for harmonization

(ii) Standard for bitterness as per WHO guideline is ————————

(a) Quinine

(b) Digoxin

(c) Reserpine

(d) Vinblastine

(iii) The residue remaining after incineration is called as ————————

(a) Foreign matter

(b) Mucilage

(c) Extract

(d) Ash

[Turn over

(iv) Which of the following is the principle of separation in Column chromatography?

(a) Electronic transition

(b) Adsorption

(c) Absorption

(d) Distribution

(v) Extractive value of crude drug determine the

(a) Organic constituents

(b) Inorganic constituents

(c) Chemical constituents

(d) Mucilage content

(vi) As per WHO guideline for evaluation of total phenol/polyphenol content one of the following reagent is used.

(a) Ferrous sulphate

(b) Ninhydrine reagent

(c) Folin-Ciocalteu reagent

(d) Dragendorff reagent

(vii) The haemolytic index shows:

(a) The di- and sesquiterpene content of the volatile oils

(b) The saponin content of the drugs

(c) The steroid content of the drugs

(d) The aliphatic monoterpene content of the drugs

(viii) The anthraquinone content of the drugs tested by

(a) warming with glacial acetic acid giving red precipitate.

(b) shaking the extract made by organic solvent with diluted ammonium-hydroxide the water phase gives red or orange colour.

(c) extracting with water and precipitate with lead acetate showing blue colour

(d) making a water extract which shows green colour on sulphuric acid

(ix) Which of the following physico-chemical characteristics is correct for mucilages?

(a) Foaming

(b) Specific colour

(c) Specific gravity

(d) Viscosity

(x) Which of the following is semi solid preparation?

(a) Vatika

(b) Churna

(c) Avaleha

(d) Asava

(xi) In Ayurveda 'ayus' means _____,

(a) Life

(b) Healing

(c) Science

(d) Treatment

(xii) Chromatography is a physical method that is used to separate _____

(a) Simple mixtures

(b) Complex mixtures

(c) Viscous mixtures

(d) Heavy metals

(xiii) In reverse phase chromatography the stationary phase is made of

(a) Non-polar

(b) Polar

(c) Either polar or non polar

(d) None of these

(xiv) Herbal drugs are regulated under Drug and Cosmetic Act in the year ——

(a) 1942

(b) 1945

(c) 1940

(d) 1990

(xv) Which one of the following is consider as reason for adulteration of crude drug

(a) Scarcity of the drug

(b) The high price of the drug in the market

(c) It is very common with the contraband drugs

(d) All above

(xvi) If a manufacturing company does not adhere to cGMP regulation

(a) Any drug manufactured by such company will be considered as "ADULTERATED"

(b) No action will be taken if the drug is safe

(c) The company will be closed instantly

(d) It means that there is necessarily something wrong with the drug

(xvii) Which technique is also known as colour writing?

(a) NMR

(b) Mass spectroscopy

(c) Chromatography

(d) All of the above

(xviii) During microscopic evaluation of plant material, all lignified tissues gives pink stain with

(a) HCL and Phlurogluconol

(b) $FeSO_4$ and Phlurogluconol

(c) Sudan red III

(d) Chloral hydrate solution

(xix) As per ICH guidelines the sub section Q1B deals with

(a) Stability testing of new dosage form

(b) Photo sensitivity testing

(c) Evaluation of stability data

(d) Stability testing of new drug and products

(xx) Patent is a form of

(a) Tangible property

(b) Intellectual property

(c) Industrial property

(d) Both (b) and (c)

2. Answer *any seven* questions : (7 × 5 = 35)

(a) What is cGMP? Discuss the WHO Guideline on cGMP of Herbal drugs. (1+4)

(b) Describe the applications of HPLC and HPTLC techniques in the standardization of herbal products. (5)

(c) Enlist and explain the documents required for new drug application and export registration. (5)

(d) Explain briefly the good agriculture practices of herbal drugs. (5)

(e) Write the chemical tests for identification of different phyto-constituents. (5)

(f) Write a note on ICH guidelines for quality control of herbal drugs. (5)

(g) What is the acceptable residual limit (ARL) in herbal drugs? Write the importance of Ash Value in standardization of herbal products. (2+3)

(h) Explain the importance of biological markers in standardization of herbal products. Give the importance of heavy metal determination in herbal drugs. (3+2)

(i) Explain the different methods for stability testing of herbal drugs in detail. (5)

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

(a) What are the basic tests for drug? Explain in brief any five basic tests for dosage forms. (3+ 7)

(b) What are the GLP requirements in the traditional system of medicine? Enumerate the determination of tannin content in herbal drugs. (5+5)

(c) Explain Physico-chemical evaluation for the quality control of herbal drugs as per WHO. (10)