2023

CJ-20

Quality Control and Standardization of Herbals

(BP806ET)

Time: Three Hours **Max. Marks: 75**

Instruction to Candidates:

1. Do not write anything on question paper except Seat No.
2. All questions are compulsory.
3. Figures to right indicate full marks.
4. Students should note, no supplement will be provided.
5. Graph or diagram should be drawn with the black ink pen or black HB pencil.

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1. A) Answer all the questions. **20**

i) . In CGMP, "C" stands for _____

a) Current b) Common c) Control d) None of these

ii) Fresh herbal materials should be stored between _____

a) 0°C to 8°C b) 2°C to 15°C c) 10°C to 15°C d) 2°C to 8°C

iii) . "SOP" stands for

a) Standard Operating Personnel b) Standard Operating Procedures

c) Standard Operating Professionals d) Standard Operating Practices

iv) . Ca-oxalate crystals are present in _____

a) Flowers b) Roots c) Rhizomes d) None of these

v) . Wagner's Test is used to detect _____

a) Alkaloid b) Glycoside c) Tannins d) Resins

vi) . Numbers of animals used in Single dose toxicity studies are_____

a) Two b) Three c) Four d) Five

vii) . Tests applicable to herbal medicinal products containing herbal substances_____

a) Loss on drying b) Purity c) Uniformity of mass d) All of above

viii) . Quarantine means?

a) Storage of finished goods b) Storage of documents

c) Storage of fresh herbal materials d) Storage of reference items

ix) Magnesium Sulphate is a Sulphate_____crystals.

a) Colourless b) Green c) Red d) Yellow

x) Medicinal plants should not be grown in soil contaminated

a) Heavy metals b) Residues c) Chemicals d) All the options

xi) Ruthenium Red test is used to detect

a) Tannin b) Resins c) Gum and Mucilage d) Fixed Oils

xii) Biochemical markers are

a) Enzymes b) Proteins c) isozymes d) All the options

xiii) IDMA stands for

a) Indian Drugs Manufacturers Association b) Indian Drugs Manufacturing Association

c) Indian Drugs Manufacturers Associate d) None of these

xiv) Test parameters used for evaluation of the herbal samples are
a) Microbiological testing b) Dissolution test
c) Test for heavy metals d) All the choices

xv) Good Manufacturing Practices in Drugs and Cosmetics Act 1940 and Rules 1945
a) Schedule T b) Schedule M c) Schedule C d) Schedule V

xvi) Chromatography is a physical method used to separate and analyze.....
a) Simple mixtures b) Complex mixtures c) Viscous mixtures d) Metals

xvii) When a company wants to manufacture/import a new drug it has to apply to seek permission from
a) GEAC b) DCC c) DCGI d) None of these

xviii) DNA Marker are not affected by
a) Age b) Environmental factors c) Physiological condition of plant d) All of above

xix) A stability study is a routine procedure that ensure
a) Safety b) Efficacy c) Both of above d) Non of above

xx) Factors affecting the stability of herbal medicine
a) Physical instability b) Chemical instability
c) Environmental condition d) All of above

2. Attempt **any two** of the following. 20
i) Explain in detail about pharmacological parameter for quality controls of herbal drugs
ii) Explain in detail about methods of drug evaluations.
iii) Write in brief about EU and ICH guideline for quality controls of herbal drugs

3. Attempt **any seven** of the following. 35
i) Explain in brief about botanical parameter for quality controls of herbal drugs
ii) Explain in brief about chemical evaluation of crude drug.
iii) Discuss about traditional system of medicine.
iv) Write a note on good collection practices for medicinal plants.
v) Add a note stability testing of herbal drug .
vi) Discuss in detail about clinical trial using herbal medicines.
vii) Explain use of HPTLC in standardization of herbals.
viii) Give functions of national pharmacovigilance centers?
ix) Give the test procedure for pharmaceutical substances

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