

(3 Hours)

Total Marks: 75

Q. 1 Attempt all multiple-choice questions (MCQ)

20M

Sr No	Questions	Options
1	Aflatoxins originate from	a algae b Virus c Bacteria d Fungi
2	If entirely new variety of plant is invented having potent medicinal values, protection can be availed for the new plant under	a The Protection of Plant Varieties and Farmers' Rights Act, 2001 b The Indian Patents Act, 1970 c Geographical Indications of Goods (Registration and Protection) Act, 1999 d The Indian Wildlife (Protection) Act, 1972
3	Intentional addition of a foreign substance to increase the weight or potency of the product or to decrease its cost is termed as _____	a Mixing b Aflatoxins c Adulteration d Allied drug
4	Which of the following modern analytical instruments is used for identifying constituent with respect to retention time	a HPLC-MS-MS b Flame photometer c Colorimeter d AAS
5	Breaking load value of lipstick should be minimum _____ as per BIS standards	a 4000 b 200 c 5000 d 2
6	Heavy metals content in Skin cream should be maximum _____ parts per million as per BIS	a 500 b 200 c 1000 d 20

- 7 AFLP in DNA fingerprinting refers to -----
- a Amplified fragment length Polymorphism
 - b Associated fragment length Polymorphism
 - c Amplified full length Polymorphism
 - d Amplified figure laser Polymorphism
- 8 Piperine is a CYP metabolic enzymes inhibitor hence it is used as _____
- a drug
 - b Bioenhancer
 - c antagonist
 - d adulterant
- 9 Safety assessment of herbal drug is carried out by
- a Toxicological studies
 - b Physicochemical evaluation ash values and extractive values
 - c Authentication
 - d Organoleptic evaluation
- 10 Fluoride ion content in Non-fluoridate toothpaste should be maximum _____ parts per million as per BIS
- a 50
 - b 200
 - c 800
 - d 500
- 11 Herbal Toxicity refers to
- a the relative ability of a substance to cause adverse effects in living organisms
 - b the amount of active constituents present in the drug
 - c the amount of substance which drug yields to the solvent
 - d The amount of starch present in the drug
- 12 As per WHO guidelines Category 2 herbal medicines are _____
- a Safety established by use over long time
 - b Herbal medicines of uncertain safety
 - c Safe under specific conditions of use
 - d No safe at all

- 13 Rancidity of raw materials used in cosmetics is determined by _____
- a Peroxide value
 - b Moisture content
 - c Ash value
 - d Loss on drying
- 14 Majority of adverse events related to the use of herbal products are due to
- a bad storage conditions
 - b unskilled labour used in collection
 - c High artificial drying of drugs
 - d poor quality control tests done on herbals
- 15 Physical method used for analysis of raw materials in cosmetics is _____
- a Rancidity test
 - b Iodine value
 - c Saponification Value
 - d Moisture Content
- 16 Stability testing of herbal drugs and preparations is carried out at ---
- a 30°C/65 per cent RH
 - b 25°C/60 per cent RH
 - c 40°C/75 per cent RH
 - d 45°C/85 per cent RH
- 17 Chemical method used for analysis of raw materials in cosmetics is _____
- a Sieve Analysis
 - b Relative density
 - c Iodine Value
 - d pH
- 18 Which of the following is a commonly used method for validating the efficacy and safety of herbal therapy
- a Controlled animal studies
 - b Expert opinion
 - c Surveys
 - d Ethobotany
- 19 Which of the following regulatory bodies is responsible for overseeing the herbal industry and ensuring compliance with safety and quality standards
- a FDA
 - b WHO
 - c USDA
 - d FTC

- 20 Herbal drug monographs are published in Ayurvedic Pharmacopoeia by
- Herbal drug commission
 - Central Council for Research in Ayurvedic Sciences (CCRAS)
 - Indian Pharmacopoeia Commission (IPC)
 - World Health Organization (WHO)

Q2. Answer any TWO of the following

20M

- Explain in detail the guidelines for standardization of herbal drugs.
- Explain with suitable examples different types of drug-drug interaction. What are spontaneous reporting schemes for bio drug adverse reactions.
- Discuss Validation of Therapy & Stability testing protocols of natural products.

Q3. Answer any SEVEN of the following

35M

- Explain in detail the general methods of adulteration screening of raw materials used in cosmetic manufacture.
- Contrast & compare different parameters of any herbal drugs mentioned in IP & USP.
- Enumerate the procedure for detection of pesticides residues & heavy metals as per WHO guidelines.
- Enlist details of Regulatory requirements for setting up herbal drug Industry.
- Explain various standard specifications laid down for lipsticks & dental products.
- Explain quality specifications used for Evaluation of herbal skin cream product according to Bureau of Indian standard (BIS).
- Discuss Pharmacodynamic & Pharmacokinetic issues related Herbal remedies.
- Compare and contrast herbal medicine Vs Conventional drugs with suitable examples .
- Write protocol for Indian and International patent law for herbal drug