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Roll Number ---------- (Total Number of Questions 13) (Total number of Printed Pages 01)

Programme	B. Pharmacy
Semester	8th
Subject	Quality Control & Standardization of Herbals
Subject Code	BP806ET
Paper ID	79769
Time	3Hours
Maximum Marks	75

Instructions to Candidates: *No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.*
Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10X2=20)

1.	Give very short answers to the followings:
i.	Write the significance of Ash value.
ii.	How do you estimate number of starch grains in ginger powder?
iii.	Explain product recall as per GMP
iv.	Define GAP.
v.	What is the role of traditional knowledge in research of herbal medicine?
vi.	What are the objectives of research guidelines for herbal medicine?
vii.	Write applications of TLC and HPTLC in standardization of herbal products.
viii.	What is accelerated stability study?
ix.	What is AYUSH and give its importance.
x.	Define standardization and write its importance.

Section- B (2X10=20)

2.	Discuss WHO guidelines for Quality control of herbal drugs.
3.	What do you understand by 'Quality assurance in herbal Industry'? Explain the guidelines on cGMP for herbal medicine.
4.	What is the purpose, types of methods and parameters used in analysis of stability testing of herbal medicine?

Section- C (7X5=35)

5.	Write a note on chemical evaluation of crude drugs.
6.	Discuss briefly physico-chemical constants used in drug evaluation.
7.	Write a note on good laboratory practices (GLP)
8.	Describe the WHO guidelines for GACP of medicinal plants.
9.	Explain the importance of European medicine agency-guideline on quality of herbal medicinal products.
10.	Write a note on toxicological investigations in herbal medicine research.
11.	Write a note on new drug approval process in India.
12.	What are the regulatory requirements of herbal medicines in India?
13.	Write a note on types and applications of markers used in standardization of herbals.

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10X2=20)

1.	Give a very short answers to the followings:
i.	Define chromatographic fingerprinting.
ii.	Write a note on the authentication of medicinal plants.
iii.	Give the objectives of the Herbal Medicinal Products Committee (HMPC).
iv.	Give the significance of the ICH guidelines.
v.	Describe the method of sampling herbal drugs as per WHO guidelines.
vi.	Define Good Laboratory Practice (GLP) and current Good Manufacturing Practice (cGMP).
vii.	What is quantitative microscopy?
viii.	What is AYUSH? Explain its significance.
ix.	Compare and contrast between analytical markers and active markers.
x.	What is the Drugs and Cosmetics Act?

Section- B (2X10=20)

2.	Write a note on WHO and ICH guidelines for the quality control of herbal drugs.
3.	Explain the applications of TLC, HPTLC, and HPLC in herbal product standardization with suitable examples.
4.	Write a note on the role of cGMP, GAP, GMP, and GLP in the quality control of the herbal drugs industry in the traditional system of medicine.

Section- C (7X5=35)

5.	Write a note on the evaluation of commercial crude drugs intended for use.
6.	How can one prepare documents for a New Drug Application (NDA) and export registration?
7.	Write a note on the basic testing of drugs.
8.	Explain the importance of the European Medicines Agency's guideline on the quality of herbal medicinal products.
9.	What are the research guidelines for evaluating the safety and efficacy of herbal medicines?
10.	Give the role of chemical and biological markers in the standardization of herbal products.
11.	What are the GMP requirements for herbal medicine?
12.	Give the WHO guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants.
13.	Compare and contrast Ayurvedic and herbal pharmacopeia.

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Section- A consists of **ten questions, each carrying **2 marks** (Very Short Answer Type); **Attempt all.***
Section- B consists of **three questions**, each carrying **10 marks** (Long Answer Type); **Attempt any two.
****Section- C **consists of** nine questions, **each carrying** 5 marks **(Short Answer Type);** Attempt any seven.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	Define chromatographic fingerprinting.
ii.	Write a short note on the authentication of medicinal plants.
iii.	State the objectives of the HMPC.
iv.	Mention the significance of ICH.
v.	Describe the method of sampling herbal drugs as per WHO guidelines.
vi.	Define GLP and cGMP.
vii.	What is quantitative microscopy?
viii.	What is AYUSH? Explain its roles.
ix.	Compare in between analytical and active markers.
x.	What is the Drugs and Cosmetics Act?

Section- B **(2X10=20)**

2.	Write a note on WHO and ICH guidelines for the quality control of herbal drugs.
3.	Explain the role of chemical and biological markers in standardization, with suitable examples.
4.	Write a note on the role of cGMP, GAP, GMP, and GLP in the quality control of herbal drugs in traditional systems of medicine.

Section- C **(7X5=35)**

5.	Write a note on the evaluation of commercial crude drugs intended for use.
6.	How can one prepare documentation for a new drug application and export registration?
7.	Write a note on the basic testing of drugs.
8.	Briefly explain the importance of the European Medicines Agency guidelines on the quality of herbal medicinal products.
9.	What are the research guidelines for evaluating the safety and efficacy of herbal medicines?
10.	Give the applications of TLC and HPLC in the standardization of herbal products with suitable examples.
11.	What are the GMP requirements for herbal medicines?
12.	State the WHO guidelines on GACP for medicinal plants.
13.	Compare in between Ayurvedic and Herbal Pharmacopoeias.

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