



PAPER ID-410388

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Subject Code: BP806ET

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BPHARM
(SEM VIII) THEORY EXAMINATION 2023-24
QUALITY CONTROL AND STANDARDIZATION OF HERBAL

TIME: 3 HRS**M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief.**10 x 2 = 20**

a.	Define Ash Value.
b.	Discuss the role of markers in herbal drug analysis.
c.	Elaborate the need of documentation as per GMP guidelines.
d.	Examine the need of record book in GLP.
e.	What is eCTD?
f.	Explore various criteria of selection of research topics.
g.	Differentiate between 'NDA' and 'ANDA'.
h.	Discuss plate theory of chromatographic techniques.
i.	Define pharmacovigilance.
j.	Name any four biological markers used in herbal drug standardization.

SECTION B

2. Attempt any two parts of the following:**2 x 10 = 20**

a.	Explore WHO guidelines on GACP for medicinal plants.
b.	Write a note on quality guidelines as per ICH.
c.	Examine various types of stability testing with their need.

SECTION C

3. Attempt any five parts of the following:**7 x 5 = 35**

a.	Explain the significance and procedure for the determination of moisture content.
b.	Discuss WHO guidelines on the safety monitoring of herbal medicines.
c.	Discuss in detail the determination of volatile oil as per WHO guidelines with a suitable diagram.
d.	Examine the role of various herbal pharmacopoeias.
e.	Discuss various research guidelines for evaluating the safety and efficacy of herbals.
f.	Discuss salient features of cGMP as per WHO guidelines.
g.	Lay down the roadmap for the preparation of documents for export registration.