PAPER ID-420748

Subject Code: BP806ET

Roll No: | | | | | | | | | | | | | |

BPHARMA
(SEM VIII) THEORY EXAMINATION 2021-22
QUALITY CONTROL AND STANDARDIZATION OF HERBAL

Time: 3 Hours *Total Marks: 75*

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

SECTION: A

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

a.	Define processed and finished herb as per WHO.
b.	What is chromatographic fingerprinting?
c.	Write a note on chemical markers with examples.
d.	Write briefly about authentication of medicinal plant.
e.	Define new drug application.
f.	Write the importance of GACP.
g.	Define bitter value?
h.	Write any two adsorbents used in TLC.
i.	Define quality control and give its significance?
j.	Define export registration.

SECTION: B

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

a.	Write a comparative note on various herbal pharmacopoeia.
b.	Describe the evaluation of commercial crude drugs intended for use.
c.	Explain briefly the current good manufacturing practices (cGMP) for herbal drugs

SECTION: C

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

a.	Discuss stability testing methods and protocols for herbal medicines.
b.	Write a note on ICH guideline for quality control of herbal medicinal products
c.	What is standardization? Explain the application of HPTLC as a method for standardization.
d.	Write a note on preparation of documents for new drug application
e.	What are the regulatory requirements of herbal medicines in India
f.	Explain briefly the good agriculture practices of herbal drugs
g.	Explain the WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Printed Pages:01 *Sub Code:BP-806ET*

Paper Id: 236449 *Roll No.*

B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Time: 3 Hours ***Total Marks: 75***

Note: 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 and give its significance.
b) Discuss herbal drug standardization.
c Give applications of TLC with reference to herbal drug standardization.
d) Discuss significance of EU guidelines.
(e) Define bitterness value with example.
(f) What are the objectives of GAP?
(g) Define shelf life and give its significance.
(h)Write a note on marker compounds.
(i) What is new drug application.
(j) Give formula for Lycopodium spore method.

SECTION B

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

(a) Give a detailed note on physical evaluation of crude drugs.
(b)Discuss in detail about GMP.
(c)What are the guidelines for quality specifications of plant materials and preparations?

SECTION C

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

a Describe the basic tests for alkaloids and tannins in herbal preparations.
b)What is biological evaluation? Discuss with example.
(c) Describe the various parameters to be included in a protocol for stability testing?
(d) Discuss the role of HPLC in standardization of herbals.
(e)What is gel permeation chromatography? Give its applications.
(f) Write a note on GLP.
(g) How clinical trials could be performed in case of herbals? Discuss with example.

PAPER ID-310847

Roll No:

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.
2. Sketch a well labeled diagram wherever required.

SECTION A

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

a.	What is the roleof chemical markers instandardization of herbalproducts?
b.	Give the principle and significance of HPTLC in herbal drugs fingerprinting.
c.	Write the objectives of GLP for manufacturing of herbal medicines as per W.H.O. guidelines.
d.	How the quality control of herbal drugs is determined? Give with suitable example.
e.	What is the shelf life of herbal drugs? Give its significance.
f.	Define stomatal number and stomatal index.
g.	What are the different types of drug applications?
h.	What are the merits and demerits of chemical evaluation of herbal drugs?
i.	What is extractive value? Give the significance of solvent choice in extraction process.
j.	Differentiate between adsorption and partition chromatography with suitable examples.

SECTION B

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

a.	
b.	Explain basic principles, working and applications of various chromatographic techniques in standardization of herbal products.
c.	Write a detailed note on regulatory requirements for herbal medicines as per WHO guidelines on safety monitoring of herbal medicines.
	What are the objectives and requirements under WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines?

SECTION C

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

a.	
b.	Give the types andsignificance of microscopical evaluation in standardization of herbal drugs.
c.	
d.	What are the requirements and significance of stability testing of herbal medicines?
	Write about the significance and applications of clinical trials in case of herbals?
e.	What are the research guidelines for evaluating the safety and efficacy of Herbal Medicines?
f.	What are the requirements of documents for new drug application as per D&C act provisions?
g.	Write a short note on biological markers in standardization of herbal products?
	Discuss the general requirements of quality assurance in herbal drug industry.

Paper ID : 250387

Roll No: | | | | | | | | | | | | | |

BPHARM

(SEM VIII) THEORY EXAMINATION 2024-25

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.	What are the goals of GAP?
b.	Outline the objectives of ICH.
c.	Give the formula for the Lycopodium spore method.
d.	Explain the acute toxicity test.
e.	Outline the significance of GACP.
f.	Briefly describe the main principles and importance of HPTLC in the fingerprinting of herbal drugs.
g.	Write about the standardization of herbal drugs.
h.	Explain chromatographic fingerprinting.
i.	Explain finished and processed herbs according to WHO guidelines.
j.	Explain the new drug application.

SECTION B

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

a.	Discuss GMP in detail.
b.	Explain in brief the cGMP for herbal medications.
c.	Discuss about new drug application document preparation.

SECTION C

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

a.	Give a detailed discussion on the long-term toxicity assessment.
b.	Explain the essential standards and importance of conducting stability testing for herbal medicines.
c.	Discuss the research guidelines for assessing the safety and effectiveness of herbal remedies.
d.	Provide a brief overview of biological markers in the standardization process of herbal products.
e.	What is the fundamental concept of standardization? Describe how HPTLC can be utilized as a technique for standardization.
f.	Sumarise good agriculture practices of herbal drugs.
g.	Describe the GMP requirements for herbal products?

Paper ID : 261660

Subject Code:BP806ET

Roll No:

BPHARM
(SEM. VIII) THEORY EXAMINATION 2025-26
QUALITY CONTROL AND STANDARDIZATION OF HERBAL

TIME: 3 HRS M.MARKS: 75

Note: Attempt all Sections.

SECTION A

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

a.	Define adulteration incrudedrugs.
b.	What is ash value?
c.	Define Good Agricultural Practices (GAP).
d.	What is marker compound?
e.	Define pharmacopoeial standards.
f.	What is stability testing?
g.	Define chromatographic fingerprinting.
h.	What is export registration of herbal products?
i.	Define biological markers.
j.	What is pharmacovigilance in herbal medicines?

SECTION B

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

a.	Discuss evaluationmethods ofcrudedrugs includingphysical,chemicaland biological parameters.
b.	Explain WHO guidelines for cultivation and collection of medicinal plants.
c.	Describe various chromatographic techniques used in standardization of herbal drugs.

SECTION C

3. Attemptany five of the following: 7 x 5 = 35

a.	Explain different types of adulteration in herbal drugs with examples.
b.	Discuss role of cGMP in herbal drug industry.
c	Describe EU guidelines for quality control of herbal medicines.
d	Write a note on stability testing protocols for herbal formulations.
e	Explain documentation required for new drug application of herbal products.
f	Explain role of chemical and biological markers in standardization
g	Discuss comparison between different herbal pharmacopoeias