JHARKHAND Rai University
RANCHI

End Semester/Reappear (Semester VIII) Examination May 2025

Programme: B. Pharm
Course: Quality Control and Standardization of Herbals **Full Marks: 75**
Course Code:BP806 ET **Time: 3 Hrs.**
Enrolment no. _____

Q.No.	Questions	CO	Bloom Taxonomy Category	Marks
	Section I			
1	**Objective Type Questions**			**1 x 20 = 20**
	i.The primary purpose of Good Agricultural Practices (GAP) in herbal drug production is to: a. Ensure the use of synthetic fertilizers b. Standardize cultivation and harvesting processes c. Promote genetically modified organisms d. Regulate pharmaceutical marketing strategies ii.The WHO guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants emphasize: a. The use of chemical pesticides b. Sustainable harvesting methods c. Exclusive reliance on wild plant sources d. Prioritizing high-yield over quality iii. According to WHO guidelines, documentation in GMP should: a. Be optional and flexible b. Provide a history of each batch of product c. Focus solely on financial records d. Be discarded after product release iv.The 'ash value' of a crude drug is determined to assess: a. The amount of organic matter b. The presence of inorganic salts c. The moisture content d. The extractive value v. The evaluation of commercial crude drugs intended for assessing: a. Organoleptic properties b. Microscopic characteristics c. Chemical constituents d. All of the above vi. The ICH guideline that focuses on stability testing of new drug substances and products is: a. ICH Q3C b. ICH Q1A(R2) c. ICH M4 d. ICH Q10 vii.WHO defines herbal medicines as products containing plant materials as: a. Active constituents b. Inactive agents c. Antioxidants d. Preservatives viii. In WHO guidelines, the first step for herbal medicine evaluation is: a. In vivo study b. Botanical identification c. Clinical trial d. HPLC analysis ix. The EU's Committee on Herbal Medicinal Products (HMPC) operates under: a. WHO b. ICH c. EMA d. FDA x. Which ICH guideline is primarily referred for stability testing of herbal products? a. ICH Q6B b. ICH Q10 c. ICH Q1A(R2) d. ICH Q2(R1) xi.In herbal drug standardization, HPTLC is preferred over TLC due to: a. Higher sample loading capacity b. Requirement of larger solvent volumes c. Enhanced resolution and quantification ability d. Lack of detection options xii.In the context of herbal drug applications, CTD stands for: a. Current Technical Directive b. Certified Technical Document c. Common Technical Document d. Chemical Testing Directive. xiii.Which international organization has issued specific guidelines on the safety monitoring of herbal medicines? a. ICH b. WHO c. FDA d. EMA xiv. A key limitation of herbal pharmacopoeias globally is: a. Use of synthetic references b. Over-reliance on chromatography c. Lack of harmonization across countries d. Too much emphasis on biological tests xv.The WHO recommends inclusion of herbal medicine safety monitoring in: a. Only developed countries b. Export certification protocols c. National pharmacovigilance programs d. Schedule H regulations	CO1	Remember	

	xvi.The role of chemical markers in standardization is primarily to: a. Predict therapeutic activity b. Ensure batch-to-batch consistency c. Validate clinical trial protocols d. Replace need for biological testing xvii.As per Schedule T of the Drugs & Cosmetics Act, the minimum area requirement for quality control section in an Ayurvedic GMP-certified unit is: a. 100 sq. ft. b. 75 sq. ft. c. 150 sq. ft. d. 200 sq. ft. xviii. In the context of herbal drug standardization, 'GMP' stands for: a. General Manufacturing Process b. Good Marketing Practices c. Good Manufacturing Practices d. General Medicinal Protocols xix.Which of the following is NOT a basic test for evaluating pharmaceutical substances? a. Macroscopic examination b. Determination of ash value c. Determination of melting point d. Determination of bitterness value xx.The ICH guideline for impurities in new drug substances is discussed under : a. Q3A(R2) b. Q6A c. Q2(R1) d. Q5E			
Section II				
2. Short Answer type questions.				**7 x 5 = 35**
a	Explain the identity test for CAPTOPRIL with it's uses	CO1	Remember	
b	Describe the role of spectroscopy techniques in the standardization of herbal drugs.	CO2	Remember	
c	Briefly describe the main objectives of the European Union (EU) guidelines for the quality control of herbal drugs.	CO3	Understand	
d	What are the different categories of stability studies performed on herbal formulations?	CO4	Remember	
e	Write the full form of AYUSH and state its regulatory role.	CO5	Remember	
f	Write a short note on the GMP requirements for Ayurvedic drugs as per Schedule T.	CO4	Remember	
	or			
	Mention the key provisions related to herbal medicines under the Drugs and Cosmetics Act.	CO4	Remember	
g	Explain in detail about the criteria and guidelines and importance of -GLP(Good Laboratory Practice).	CO2	Remember	
	or			
	Explain in detail about the criteria and guidelines and importance of -GACP	CO2	Remember	
Section III				
Long Answer Type questions				**2 x 10 = 20**
3	Evaluate the effect of BITTERNESS VALUE with their examples and identification methods in herbal drugs. Highlight the basic concept of Radioactive contamination.	CO1	Evaluate	
	or			
	Evaluate the risks associated with aflatoxins in herbal drugs. Critically assess the effectiveness of the HPLC method with fluorescence detection for their analysis in herbal products.	CO1	Evaluate	
4	Analyze the challenges faced by regulatory authorities in harmonizing international guidelines (EU, ICH, WHO) for herbal drug quality control. What strategies could be implemented to overcome these challenges?	CO3	Analyze	
	or			
	Illustrate the role of Good Agricultural and Collection Practices (GACP) as recommended by the EU guidelines in maintaining the quality of herbal medicinal products. How does GACP contribute to the overall safety and efficacy of these products?	CO3	Evaluate	

Course Outcomes (CO):

- CO1: To understand WHO guidelines for quality control of herbal drugs
- CO 2.To understand Quality assurance in herbal drug industry
- CO 3.To understand the regulatory approval process and their registration in Indian and international markets
- CO 4. To understand the appreciate EU and ICH guidelines for quality control of herbal drugs
- CO 5: To understand Regulatory requirements for herbal medicines and WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.