THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[BPHARM0422] APRIL 2022 Sub. Code: 2082
(SEPTEMBER 2021 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 SEMESTER VIII
PAPER VI QUALITY CONTROL AND STANDARDIZATION OF HERBALS
Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Describe the guidelines on GACP for medicinal plants.
2. Explain the quality control of herbal drugs as per WHO guidelines.
3. Enumerate the regulatory requirement of herbal drugs.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Explain the various herbal pharmacopoeias.
2. Write the GMP requirement for herbal medicine.
3. Explain the preparation of document for new drug application.
4. Discuss the protocol for clinical guidelines in herbal medicine.
5. Enumerate various aspects of GLP.
6. Write the applications of chromatography technique its standardization of herbal drugs.
7. Write briefly about stability studies of herbal medicinal products.
8. Describe the basic test for medicinal plant materials.
9. Write a note on research guidelines for evaluating safety and efficacy of herbal medicine.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Natural pesticide.
2. Difference between TLC & HPTLC.
3. Types of markers with examples.
4. Extractive value and its significance.
5. Define SOP.
6. What is AYUSH?
7. Examples of herbal drug interaction.
8. Significance of ICH.
9. Define term herbal medicine & crude drug.
10. Quantitative microscopy.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[BPHARM 1022] OCTOBER 2022 Sub. Code: 2082
(MARCH 2022 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VI - QUALITY CONTROL AND STANDARDIZATION OF HERBALS
Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Describe WHO guidelines for quality control of herbal drugs.
2. Explain the infra structural requirements under GMP for herbal industry.
3. Describe the preparation of documents for new drug application and export registration.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. What is GAP? Explain the various parameter of GAP.
2. Explain the importance of HPTLC method in the standardization of herbal drugs.
3. Write a note on regulatory requirement for herbal drugs.
4. Describe the guidelines on safety and efficacy of herbal medicine.
5. Explain WHO guidelines on current good manufacturing practices for herbal medicine.
6. Discuss about the assessment of Genotoxicity of herbal preparations.
7. Define and classify markers with examples.
8. Describe the basic test for medicinal plant material.
9. Explain ICH guidelines for the quality control of herbal drugs.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Write note on Pharmacovigilance.
2. Shelf life and significance.
3. Ash values and significance.
4. List out Chromatography techniques used in herbal standardization.
5. Define Teratogenecity.
6. Quantitative Microscopy.
7. Define standardization of herbal.
8. Traditional medicine.
9. Define GACP and its significance.
10. Method of drying and its significance.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0323] MARCH 2023 Sub. Code: 2082
(SEPTEMBER 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS
Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Write a detailed note on preparation of documents for New Drug Application.
2. Explain ICH guidelines for quality control of herbal drugs.
3. Discuss in detail WHO guidelines for quality control of herbal drugs.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Physical evaluation of crude drugs.
2. Application of HPTLC in the standardization of herbal drugs.
3. GLP in the traditional system of Medicine.
4. Research guidelines for evaluation of efficacy of herbal medicines.
5. Challenges in monitoring adverse drug reaction in herbal medicines.
6. Identification test for alkaloids.
7. WHO guidelines on GACP for medicinal plants.
8. Guidelines on clinical assessment of fixed combination of herbal preparation.
9. Comparative study of African Herbal Pharmacopoeia and British Herbal Pharmacopoeia.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Define Palisade Ratio.
2. Different types of Stomata.
3. Application of Gas Chromatography.
4. Secondary processing of medicinal plants.
5. Authentication of medicinal plants.
6. Identification test for glycosides.
7. Lycopodium Spore Method – Formula.
8. Examples of herbal drug interaction.
9. What are weedicides? Mention two examples.
10. Test for teratogenicity.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2082
(MARCH 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Describe chromatography techniques in the standardization of herbal drugs.
2. What do you understand by quality assurance in herbal industry? Explain the importance of GMP in herbal industry.
3. Write about European medicine agency (EMA). Enumerate the European guidelines on quality of herbal medicinal product.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Define and classify markers with examples.
2. Explain the procedure and significance on microscopical evaluation of herbal drugs.
3. Enlist the document required for export registration.
4. Write note on ICH guidelines.
5. Give the clinical guidelines on assessment of safety and efficacy of herbal medicine.
6. Write a note on good practice for harvesting and storage of herbal products.
7. What is traditional system of medicine? What are the GLP requirements in traditional system of medicine?
8. Explain the protocol for stability testing of herbal medicines.
9. What are the basic test for alkaloids and glycosides in herbal products?

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. What are pesticides? Give two examples.
2. Define processed and finished herb as per WHO.
3. Swelling factor and its significance.
4. Components of HPLC.
5. Define TLC and HPTLC.
6. Authentication of medicinal plants.
7. Importance of ash values.
8. List out any four Pharmacopoeia.
9. Examples of herbal drug interaction.
10. Define shelf life.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2082
(SEPTEMBER 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Explain the role of chemical and biological markers in standardization of herbal products.
2. Write a detailed note on the preparation of documents for export registration.
3. Explain WHO guidelines on current good manufacturing practices of herbal medicines.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Morphological evaluation of crude drugs.
2. Good Agricultural Practices of herbal drugs.
3. Systematic Quality Control analysis of Senna leaf.
4. Research guidelines for evaluation of herbal medicines.
5. Stores under GMP in herbal drug industry.
6. Infrastructural requirements under GMP of herbal drugs.
7. Comparative study of American Herbal Pharmacopoeia and Indian Herbal Pharmacopoeia.
8. Quality Assurance in herbal drug industry.
9. Good practices for the storage of herbal medicinal products.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Define Swelling index.
2. Different types of trichomes.
3. Significance of SOP.
4. Define Quantified Herbal Substances.
5. Any two Harvesting Methods of Medicinal Plants.
6. Primary processing of medicinal plants.
7. What is chemo microscopy?
8. Define shelf-life and give its significance.
9. Acute Toxicity Test.
10. Identification test for genotoxic constituents.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0524] **MAY 2024** **Sub. Code: 2082**

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. GACP for Medicinal Plants as per WHO Guidelines.
2. Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.
3. Applications of various Chromatographic Techniques in Standardization of Herbal Products.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. WHO Guidelines for general limits for Contaminants in Herbal Drugs.
2. Chemical Methods of Evaluation of Crude Drugs with examples.
3. Selection of Medicinal Plant for Collection.
4. Guidelines for Toxicity Investigation of Herbal Medicines.
5. Analytical Methods to determine the Stability of Herbal Products.
6. Infra Structural Requirements under GMP for Herbal Drug Industry.
7. Quality Audit.
8. Role of Markers in Standardization of Herbal Products.
9. Herbal Medicinal Product Development.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Lycopodium Spore Method.
2. Test Procedure for Senna Leaf.
3. Good Collection Practices.
4. Good Laboratory Practices.
5. ICH parties.
6. New Drug Application.
7. Herbal Pharmacopoeia.
8. Basic test for Amikacin Sulphate.
9. Stomatal Index.
10. Genotoxicity.

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THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2082
(SEPTEMBER 2024 EXAM SESSION)

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 X 10 = 20)**

1. Discuss in brief about the various Evaluation Parameters used for Quality Control of Herbal Drugs.
2. Discuss WHO Guidelines on the Current Good Manufacturing Practices for Herbal Drugs.
3. Explain the Standards of Drugs as per Existing Legislature of India. Enlist the Factors to be Considered for Registration of Herbal Medicine across the Globe.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Comparison of various Herbal Pharmacopoeias.
2. Good Laboratory Practices.
3. Common Technical Aspects of Good Agricultural and Collection Practices for Medicinal Plants.
4. Write short note on Control of Starting Materials.
5. Clinical trials using Herbal Medicine.
6. Types of Stability Testing.
7. Short note on Thin Layer Chromatography.
8. Export Registration.
9. Safety Monitoring of Herbal Medicines.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Ipecacuanha Root.
2. Stomata and its functions.
3. Herbal Medicine.
4. Drug Extract Ratio.
5. Markers.
6. Shelf Life.
7. Pharmaceutical substance.
8. MedDRA.
9. Selection of Medicinal Plants for Collection.
10. ICH.

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0925] SEPTEMBER 2025 Sub. Code: 2082

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER III - QUALITY CONTROL AND STANDARDIZATION OF HERBALS
Q.P. Code: 562082

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Define the term 'PHARMACOPOEIA'. List out and compare various herbal pharmacopoeias with its advantages and disadvantages.
2. Define evaluation. Discuss the various evaluation parameters. How will you evaluate Toxic residues and microbial contamination?
3. Discuss the Regulatory requirements of Indian system of medicines. Discuss about DTAB and DCC of ISM.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Write a note on 'Complaints' as per WHO issued guidelines on CGMP.
2. Discuss about Schedule – T.
3. What are herbal markers? Write the advantages of herbal markers with examples.
4. What are the research guidelines applied to ensure the safety and efficacy of herbal medicines?
5. How the chromatographic techniques helpful in standardizing the herbal drugs?
6. Discuss the procedures of herbal monographs in standardizing and evaluating marketed herbal products.
7. Enumerate the ICH guidelines requirements of herbal drugs.
8. Write about GACP of herbal products.
9. How will you prepare applications for NDA and ANDA?

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. What is Pharmacovigilance?
2. Types of toxicity models.
3. Leaf constants and ash values.
4. What are aflatoxins? How its produced?
5. Identification test for Podophyllum resin and Ipecacuanha.
6. Biological evaluation tests.
7. Write about shelf life and its significance.
8. Evaluation of pesticide residues in herbals.
9. Write about Trigunas and Tridhosic principles.
10. What are Archival and review copy of NDA?

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