

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

[BPHARM0422]

**APRIL 2022
(SEPTEMBER 2021 SESSION)**

Sub. Code: 2082

**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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[BPHARM 1022]

**OCTOBER 2022
(MARCH 2022 SESSION)**

Sub. Code: 2082

**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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[B.PHARM 0323]

**MARCH 2023
(SEPTEMBER 2022 EXAM SESSION)**

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. 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.
