

MAY 2011

[KY 353]

Sub. Code: 2914

M.PHARM. DEGREE EXAMINATION

(Regulations 2010)

(Candidates admitted from 2010-2011 onwards)

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262914

Time : Three hours

Maximum : 100 marks

Answer All questions

I. Essay Questions : (6 x 10 = 60)

1. Explain any two drugs official in IP assay principle and procedure by UV and HPLC method.
2. Describe about ICH guidelines for impurities.
3. Explain any two preservatives identification and quantification test.
4. Discuss about ISI specification of quality of perfumes and colourants raw materials used in cosmetics.
5. Explain toxicity testing of cosmetics.
6. Discuss about ISI specification of high grade soap.

II. Write Short Notes : (8 x 5 = 40)

1. Antioxidants used in pharmaceuticals.
2. Radio chemical methods in analysis.
3. Accelerative stability studies.
4. QC of injections.
5. ISI specification of nail polish.
6. ISI specification of skin powders
7. Surfactants raw material used in cosmetics.
8. ISI specification of baby shampoo.

October 2011

[KZ 353]

Sub. Code: 2914

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS
Q.P. Code : 262914

Time : 3 hours
(180 Min)

Maximum : 100 marks

Answer ALL questions in the same order.

I. Elaborate on :

	Pages	Time	Marks
	(Max.)	(Max.)	(Max.)
1. Explain the principle and procedure involved in the official assay of (i). Allopurinol (ii). Metronidzol (iii) Piperazine 4. Verapamil.	17	40	20
2. Write a note on different raw materials used in cosmetics?	17	40	20

II. Write notes on :

1. How will you perform the test for toxicity in cosmetics?	4	10	6
2. Enumerate the Indian Standard specifications of nail polish?	4	10	6
3. List out the various Quality control test of tablets?	4	10	6
4. Describe about the water raw material purification methods involved in quality control?	4	10	6
5. Enumerate in detail about the sampling process of biological sample?	4	10	6
6. Identification and Quantitative determination of any two preservatives?	4	10	6
7. Write an account on cosmetic legislation?	4	10	6
8. Describe the quality control tests for ointments?	4	10	6
9. Explain the diazotization titration with example?	4	10	6
10. Explain the principle and procedure involved in the IP official assay of (i) Ibuprofen (ii) Tolbutamide.	4	10	6

[LA 353]

MAY 2012

Sub. Code: 2914

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code: 262914

**Time: 3 hours
(180 Min)**

Maximum: 100 marks

Answer ALL questions in the same order.

I. Elaborate on:

**Pages Time Marks
(Max.) (Max.) (Max.)**

- | | | | |
|---|----|----|----|
| 1. Write in detail discussion on in process quality control test for the following pharmaceutical dosage forms (i) Parenterals (ii) Tablets. | 17 | 40 | 20 |
| 2. Explain the different methods of analysis to assess the quality of the following cosmetic products.
(i) Lipsticks (ii) Hair care Products (iii) Baby Powder (iv) Dental products. | 17 | 40 | 20 |

II. Write notes on :

- | | | | |
|---|---|----|---|
| 1. Explain principle and procedure involved in the official (IP 1996) assays of (i) Calcium gluconate tablets (ii) Chloramphenicol eye drops. | 4 | 10 | 6 |
| 2. List out different solvents used in cosmetics and discuss quality control test for any one of solvent used in cosmetics. | 4 | 10 | 6 |
| 3. How do you determine microbial contamination in cosmetics? | 4 | 10 | 6 |
| 4. Explain the method of identification and determination of any two antioxidants. | 4 | 10 | 6 |
| 5. Write ICH guidelines for related substance and impurity detection in drugs. | 4 | 10 | 6 |
| 6. Explain toxicity testing of cosmetics. | 4 | 10 | 6 |
| 7. BIS specification for Shampoo. | 4 | 10 | 6 |
| 8. Discuss in process quality control test for ointments. | 4 | 10 | 6 |
| 9. Discuss ICH guidelines for stability studies of drugs. | 4 | 10 | 6 |
| 10. Explain various extraction process involved in biological sample analysis and their limitation and applications. | 4 | 10 | 6 |

[LB 353]

NOVEMBER 2012
M.PHARM. DEGREE EXAMS
FIRST YEAR

Sub. Code: 2914

BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS
Q.P. Code : 262914

Time : 3 hours
(180 Min)

Maximum : 100 marks

Answer ALL questions in the same order.

I. Elaborate on :

	Pages (Max.)	Time (Max.)	Marks (Max.)
1. In detail explain the identification and qualitative determination of antioxidants used in pharmaceutical preparations.	17	40	20
2. What are the procedures used for the extraction of drugs from biological samples and explain the factors affecting extraction procedures.	17	40	20

II. Write Notes on :

1. How is the toxicity testing done for cosmetics?	4	10	6
2. Write the method for determination of related substances present in metronidazole IP and paracetamol IP.	4	10	6
3. What are the in process quality control tests carried out for different types of capsules?	4	10	6
4. What are radio pharmaceuticals? How does the quality of them determined?	4	10	6
5. What are the raw materials used in cosmetics? Explain quality control two of them.	4	10	6
6. How is the QC test for controlled release dosage forms performed?	4	10	6
7. List out the preservatives used in pharmaceutical preparations, giving their limit and estimation procedures.	4	10	6
8. Explain with few examples how the Complexometric titration utilized for the estimation of official compounds.	4	10	6
9. What is shelf life of formulations? How shelf life is predicted with accelerated stability testing?	4	10	6
10. Write on testing of color cosmetics.	4	10	6

[LC 353]

APRIL 2013

Sub. Code: 2914

M.PHARM. DEGREE EXAMS

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262914

Time : 3 hours

Maximum : 100 marks

I. Elaborate on :

(2x20=40)

1. Explain the principle and procedure involved in the official (IP 1996) assays of the following drugs.
 - a. Dapsone tablets
 - b. Phenytoin sodium tablets
 - c. Paracetamol tablets.
 - d. Captopril tablets.

2. Write in detail about in process quality control test for the followings :
 - a. Tablets.
 - b. Suppositories.

II. Write Notes on :

(10x6=60)

1. Write a note on different raw materials used in cosmetics.
2. Write briefly stability testing for pharmaceutical dosage forms.
3. Write identification and quantification for Butylated Hydroxy Anisole.
4. How do you determine the quality of tooth powder?
5. Discuss toxicity testing in cosmetics.
6. Enumerate principle involved in Liquid-Liquid extraction process and discuss factors affecting extraction.
7. Explain quality control test for lipsticks.
8. List out different preservatives used in pharmaceutical formulation and give an estimation of sodium benzoate.
9. Write ICH guidelines for related substance and impurity detection in drugs.
10. Explain sodium sulfate determination in Shampoo.

[LD 353]

OCTOBER 2013

Sub. Code: 2914

M.PHARM. DEGREE EXAMINATIONS
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262914

Time: Three Hours

Maximum: 100 marks

Answer ALL questions in the same order.

I. Elaborate on :

(2 x 20 = 40)

1. Explain the identification and quantitative determination for few of the following additives used in formulations.
 - i) Emulsifiers and stabilizers
 - ii) Preservatives
2. Give in detail on the analysis of various raw materials used in cosmetic preparations.

II. Write notes on :

(10 x 6 = 60)

1. Describe the in process quality control tests employed for controlled released products.
2. Write on any TWO radio pharmaceutical components used for the treatment of diseases.
3. With example write on the principle and practice of gravimetric methods for assaying official compounds.
4. Give a note on the residual solvent determination according to ICH guidelines.
5. Explain various quality control tests employed for shampoos.
6. Briefly add note on accelerated stability testing and its limitation.
7. Write on evaluation of parenteral and sterile products.
8. How and why skin irritation tests are carried out for cosmetic products?
9. How does extraction of drugs carried out by Liquid Extraction?
10. Explain principle & procedure of drugs assayed by UV spectroscopic methods with suitable examples.

[LE 353]

APRIL 2014

Sub. Code: 2914

**M.PHARM. DEGREE EXAMS
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

Q.P. Code : 262914

Time : 3 hours

Maximum : 100 marks

I. Elaborate on :

(2x20=40)

1. What are impurities? Write in detail on ICH guidelines for the determination of impurities and related substances present in drugs.
2. According to IP'96 explain the principle and procedure involved in the assay of following
 - i) Metronidazole tablets ii) Metformin HCl tablets iii) Diclofenac sodium tablets iv) Riboflavin.

II. Write notes on :

(10x6=60)

1. How the stability testing does carry out to predict shelf life formulations?
2. What are the factors affecting extraction of drugs from biological samples by LLE methods?
3. How does the cosmetics are tested for their suitability to be used on skin applications?
4. What is the importance of radio pharmaceuticals? Give the quality control tests for sodium iodide (^{131}I) injection.
5. According to BIS how the quality of water and glycerol used in cosmetic preparations was determined?
6. Write on the principle and practice of solid phase extraction of drugs from biological fluids.
7. Explain the sampling and finished product analysis of hair care preparations.
8. Write on use and determination of benzyl chloride and methyl paraben used in pharmaceutical products.
9. Explain various factors used in quality control test of tablets.
10. How does the quality of baby care products ascertained?

[LF 353]

OCTOBER 2014

Sub. Code: 2914

**M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

Q.P. Code : 262914

Time : Three hours

Maximum : 100 marks

I. Elaborate on:

(2 x 20 = 40)

1. a) Write the principle, reaction and procedure involved in the assay of the following drugs: a) calcium lactate tablets b) tolbutamide tablets.
b) Explain the principle, reaction, procedure and method of assay involved in the determination of Piperazine citrate.
2. Elaborate the related substances and impurities present in drugs. Add a note on their effect on drug stability and therapeutic action.

II. Write notes on:

(10 x 6 = 60)

1. Explain the in process quality control of cream preparation.
2. State the methods of extraction of drugs from biological sample.
3. Write a note on quality control of radio pharmaceutical.
4. Specify the significant of accelerated stability and analysis.
5. Explain in detail Quality control tests for the coated and uncoated tablets with the specifications as stated in pharmacopoeias.
6. Enumerate the Methods of test for nail polish.
7. Write in brief on quality control test for dental products.
8. Write a note on preservative raw material used in cosmetics.
9. How will you determine the related substance present in Albendazole and diclofenac as per IP?
10. Discuss the ICH guidelines for stability studies of drugs.
