SEPTEMBER 2007

[KR 328] **Sub. Code : 2864**

M.Pharm. DEGREE EXAMINATION.

First Year

(Regulations 2006)

Branch V — Pharmaceutical Analysis

Paper II — PHARMACEUTICAL AND COSMETIC ANALYSIS

Time : Three hours | Maximum : 100 marks

Theory : Two hours and forty minutes | Theory : 80 marks

M.C.Q. : Twenty minutes | M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

1. (a) What are the sources for related substances and impurities present in drugs? Give any four examples for such related substances and impurities.

(b) What is the effect of impurities on drug stability and therapeutic actions? (10 + 10)

2. Explain the principles with equations, if any and procedures involved in the assay of any one drug official in I.P. for the following :

(a) Non aqueous titrations using sodium methoxide titrant.

(b) Complexometric back titration

(c) UV – Extinction method. (5 + 5 + 5)

3. (a) Why is it necessary to determine quality of raw materials used in manufacturing of cosmetics?

(b) Enumerate any one example each for drug along with methodology in brief, that are extracted by LLE and SPE methods. (10 + 5)

II. Short notes : (6 × 5 = 30)

1. With examples explain the principle involved in Diazotization titration?

2. What are Radiopharmaceuticals? Write the general Q.C. tests for Radiopharmaceuticals.

3. Write methods to analyze the quality of various Personal hygiene products.

4. Write a note on IPQC tests for sterile preparations.

5. What are the various antioxidants and colouring materials used in pharmaceutical formulations?

6. Why is it essential to test for toxicity in cosmetic preparations?

September 2008

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Q.P. Code : 262864

Time : Three hours Maximum : 100 marks

Answer ALL questions.

I. Long Essay : (3 × 20 = 60)

1. Add a detail note

(a) Stability testing protocol for pharmaceutical products.

(b) Toxicity testing in cosmetics. (12 + 8)

2. Explain the different methods of analysis to determine the quality of the following finished cosmetic products.

(a) Hair care products.

(b) Personal hygiene products.

(c) Hair setting lotions.

(d) Eye shadows. (4 × 5 = 20)

3. Explain the principle and procedure involved in the official assays of

(a) Allopurinol tablets.

(b) Metronidazole tablets.

(c) Piperazine phosphate tablets.

(d) Verapamil tablets. (4 × 5 = 20)

II. Short notes : (8 × 5 = 40)

1. Enumerate different radiochemical methods useful in analysis of drugs.

2. Give an account on shelf life prediction.

3. Write a note on different excipients used in cosmetics.

4. Explain the methods of identifications and determination of antioxidants.

5. List out different methods of drugs extraction and add a note on membrane filtration.

6. Add a note on the significance of Accelerated stability analysis.

7. How do you determine the quality of raw materials in cosmetic industry?

8. Write a note on in process quality control testing of sterile preparations.

March 2009

[KU 328] **Sub. Code: 2864**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262864

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. What are in-process quality control tests? What in-process quality control tests are carried out for tablet dosage forms and parenteral preparations?

2. Write the principle and procedures involved in the assay of the following drugs (IP):
   a) Benzocaine **b)** Magnesium sulphate **c)** Ibuprofen **d)** Tolbutamide

3. Explain the impact of drug impurities in stability of drugs and its therapeutic action. Write on ICH guidelines for impurity determination in drugs.

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

1. Write a note on quality control of radiopharmaceuticals.
2. Describe the quality control tests for controlled release products.
3. What is shelf life prediction? How is it carried out for life saving drugs?
4. Write methods for extraction of drugs from biological samples.
5. How is the efficacy of baby care products determined?
6. Write quality control tests for dental products.
7. Write a note on toxicity testing in cosmetics.
8. What are personal hygiene products? How are their quality determined?

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September 2009

[KV 328] **Sub. Code: 2864**

M.PHARM. DEGREE EXAMINATION

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FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262864

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Explain the principle and method of assay involved in the determination of the following drugs:
   a) Chloroquine phosphate inj. **b)** Calcium Gluconate tablets.
   c) Sulphadiazine tablets **d)** Frusemide injection

2. Give a detailed note on the Indian standard specifications (ISI) recommended for sampling and testing by the bureau of Indian standards for the cosmetics in the finished products.

3. How the quality of the following cosmetics in the finished forms are determined?
   a) Skin care products **b)** Dental products **c)** Lip sticks **d)** Eye shadows.

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

1. How the dyes soluble in both water and alcohol are determined?
2. How the antioxidants present in pharmaceutical formulations are identified and determined?
3. What are the various procedures in quality control tests carried on tablets?
4. How membrane filtration is useful in the extraction of drugs? Add a note on the factors effecting the extraction of drugs.
5. Write a note on ICH guidelines for the determination of impurities and related substances in drugs.
6. How the toxicity is tested in cosmetics?
7. Write a note on applications of radio chemical methods in analysis.
8. Give an account on safety and legislation of cosmetic products.

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March 2010

[KW 328] **Sub. Code: 2864**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262864

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Explain the principle and method of assay involved in the determination of the following drugs:
   a) Ephhedrine HCI tablets **b)** Tolbutamide.
   c) Ibuprofen **d)** Paracetamol tablets

2. a) Write a detailed notes on ICH guidelines for the determination of impurities and related substances in drugs.
   b) What are the in process quality control tests performed in Tablets.

3. How the quality of the following cosmetics in the finished forms are determined?
   a) Bay care products **b)** Personal hygiene products
   c) Colour cosmetics **d)** Hair care products.

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

1. What is the possible impurity present in light kaolin and it is determined?
2. What are the in process quality control tests performed on parenteral and sterile preparations?
3. Give the methods of detection and determination of antioxidants in pharmaceutical formulations.
4. What are the specifications recommended by the Bureau of Indian standards for shampoos?
5. What are the various methods of extraction for drugs? Add a note on the factors effecting the extraction of drugs.
6. Trough light on safety and legislation of cosmetic products.
7. Give the general methods of analysis to determine the quality of raw materials.
8. Give an account of quality control of Radio pharmaceuticals.

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September 2010

[KX 328] **Sub. Code: 2864**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

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FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262864

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Give an account on the specification recommended by Bureau of Indian standards for the cosmetics. How the following are determined a) Face Powder b) Shampoo.

2. What is Indian standard specifications (151)? Discuss the methodology involver for sampling and testing by the Indian standards for cosmetics in the finished products.

3. a) What are complexometric titrations.
   b) Give an account on the stability of EDTA metal complex with reference to pH influence.

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

1. Write the principle, endpoint determination and applications of potentiometry.
2. Write identification and quantitative determination of coloring materials in formulations.
3. Write the principles and procedure involved for the assay of any one drug each by non-aqueous and gravimetric method.
4. What are diazotizations? How do you determine the endpoint in such methods? Write applications of this method.
5. Write quality control test for Dental products.
6. How the toxicity tested in cosmetics?
7. Give an account on shelf life predictions.
8. What are personal hygiene products? How are their quality determine?

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MAY 2011

[KY 328] **Sub. Code: 2864**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

(Candidates admitted from 2006-2007 onwards)

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS

Q.P. Code : 262864

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Write the principle and procedures involved in the assay of a) Ampicillin b) Piperazine Adipate c) Pyridoxine Hydrochloride d) Sulphadiazine.
2. a) How impurities which effect drug stability and therapeutic action?
   b) Explain toxicity testing of skin care cosmetics.
3. Describe about ISI specification for sampling of various cosmetics in finished form.

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

1. Identification and quantitative determination of any two preservatives.
2. In process QC of tablets.
3. Factor affecting LLE.
4. ICH guidelines for stability studies of drugs.
5. ISI specification of Baby soap.
6. ISI specification of Nail polish.
7. ISI specification of After shave lotion
8. Humectants used in cosmetics.

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