FEBRUARY 2005

[KM 304] Sub. Code : 1024

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Sec. A & B : Two hours and forty minutes Sec. A & B : 80 marks

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

Answer ALL questions.

SECTION A — (2 × 15 = 30 marks)

Long Essay :

1. Explain the importance of packaging. How do you substantiate the features provided by a primary and secondary packaging material for maintaing high quality with respect to parenteral preparations.

2. Explain the concept of Quality Assurance. Explain the organisation and functions of a Quality Assurance Department.

SECTION B — (10 × 5 = 50 marks)

Short notes :

3. Write an account of Good Laboratory Practices.

4. Explain the organisation and functions of a Quality Control Laboratory.

5. What is a 'Product Recall'? What steps are taken during such situation?

6. What criterions are applied for selection, purchase and maintenance of equipment?

7. What are the components of a master formula record?

8. What are the limitations of accelerated stability testing?

9. Write a note on good warehousing practices.

10. What is the importance of a distribution record? How is it maintained in a pharmaceutical industry?

11. What is inprocess quality checks are carried out during the production of sterile parenteral preparations?

12. Explain the importance of standard operating procedures.

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AUGUST 2005

[KN 304] Sub. Code : 1024

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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 : (2 × 15 = 30)

1. Explain in detail the good warehousing practices.

2. What is Inprocess quality control? Discuss in detail the Inprocess quality controls on various dosage forms.

II. Short notes : (10 × 5 = 50)

1. Write notes on types of glasses used for manufacturing pharmaceutical containers.

2. Add a note on shelf life prediction.

3. What are the ICH guidelines to carryout stability testing?

4. List the functions of NABL.

5. Give an account on the quality control of packaging material.

6. Write notes on good laboratory practices.

7. What are the legal procedures in handling of returned goods?

8. Write a note on regulatory aspects of bulk drug manufacture.

9. Discuss briefly the procedure for release of finished products.

10. Write a note on quality control documentation.

MARCH 2006

[KO 304] **Sub. Code : 1024**

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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 : (2 × 15 = 30)

(1) (a) Explain the evolution of the concept of total quality management in pharmaceutical industry. (8)

(b) Explain the GMP guidelines to prevent mix up and cross contamination during production. (7)

(2) (a) Explain the salient features of quality system elements of NABL. (9)

(b) Write a note on limitations of accelerated stability testing. (6)

II. Short notes : (10 × 5 = 50)

(1) Explain the procedure in handling of returned goods.

(2) Give an account of ICH guidelines for validation of analytical methods.

(3) Add a note on ISO-9000.

(4) Explain the purchase specifications for raw materials in pharma industry.

(5) Explain the significance of batch production records.

(6) Add a brief note on the in process quality control for sterile dosage forms.

(7) Explain the pharmacopoeial tests for various glass containers.

(8) Explain the advantages of various stake holders in getting ISO certificates.

(9) Give a brief account on packaging and labelling control.

(10) Add a note on master formula record.

SEPTEMBER 2006

[KP 304] Sub. Code : 2828

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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 is Recall? What are the strategies adopted with regard to the same to find the level of effectiveness?

(b) Explain the different guidelines that are being followed with regard to the quality control of nonsterile products. (10 + 10 = 20)

2. Discuss in detail the term Good laboratory practices, stressing on the responsibilities of quality control laboratory as regards to the instruments, reagents, sampling plans, standard test procedures including the controls on animal house. (15)

3. Discuss in detail regulatory aspects with regard to pharmaceutical and drug manufacture and write in brief the regulation with regard to packaging and labelling. (15)

II. Short notes : (6 × 5 = 30)

1. Write briefly on time limitations on production.

2. Write a note on sampling and testing of in process materials and drug products.

3. Write a note on radiation sterilization.

4. Write in brief, the personnel, premises and equipment, documentation help in quality management.

5. Point out the guidelines followed in the control of components, containers and closures.

6. What are the requirements specified for ISO 9004.

MARCH 2007

[KQ 304] **Sub. Code : 2828**

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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. Write about the various concepts of total quality management and enumerate the ISO 9000 and its applicability to pharmaceuticals. (20)

2. Explain the concept of GMP with special emphasis on the premises, manufacturing operation and documentation procedures followed in pharmaceutical industry. (15)

3. Define warehousing. How do you design and construction of good warehouse. (15)

II. Short notes : (6 × 5 = 30)

(1) Stability testing studies as per ICH guidelines.

(2) Finished products release.

(3) WHO and NABL certification

(4) How do you document the complaints and recalls in industry especially in formulation unit.

(5) Handling of returned goods.

(6) SOP (Standard Operating Procedure)

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MARCH 2007

[KQ 330] **Sub. Code : 2866**

M.Pharm. DEGREE EXAMINATION.

First Year

(Regulations 2006)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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 is warehousing? Write in detail about Good Warehousing practices in large scale industry.

(b) Write in brief the recent amendments to drugs and cosmetic act and other relevant rules. (10 + 10 = 20)

2. Explain the concept of manufacturing practices, with special reference to premises, manufacturing operation and documentation procedures usually followed in pharmaceutical industry. (15)

3. Discuss in detail the term good laboratory practices, with special emphasis on the responsibilities of quality control laboratories as regard to sampling plans, instruments, standard operating procedures. (SOP's). (15)

II. Short notes : (6 × 5 = 30)

(1) Write a notes on Master formula.

(2) Write at least ten elements or criteria are followed of the ISO 9000 series standards.

(3) Point out the different guidelines that are followed with the special emphasis on non sterile products.

(4) Write briefly on loan license auditing.

(5) Write in brief about quality review and quality audits.

(6) Write in brief about scrap disposal procedures.

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SEPTEMBER 2007

[KR 304] **Sub. Code : 2827**

M.Pharm. DEGREE EXAMINATION.

First Year

(Revised Regulations)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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) What is inprocess quality control? Mention its importance. What are the inprocess quality control tests carried out for (a) parenterals and (b) capsules? (20)

(2) Explain the GMP guidelines on selection, training, health, clothing and sanitation requirements of personnel employed in pharmaceutical industries. (15)

(3) Explain the organisation and function of National Accreditation Board for testing and calibration Laboratories (NABL). Describe in brief on sampling plan. (15)

II. Short notes : (6 × 5 = 30)

(1) Explain the pharmacopoeial test for various glass containers.

(2) What is the need for distribution records in industry?

(3) List out the various responsibilities of a qualified personnel in a manufacturing unit.

(4) Write notes on various activities at different stages in total quality management.

(5) Give an account on product recall with reference to recall procedure.

(6) Discuss the ISO 9000 series standards and explain their quality elements.

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SEPTEMBER 2007

[KR 330] **Sub. Code : 2866**

M.Pharm. DEGREE EXAMINATION.

First Year

(Regulations 2006)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

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 manufacturing records? Write in details regarding the components and management of Batch Manufacturing records.

(b) Classify packaging materials used in pharmaceutical industry. What tests are carried out to ensure the quality of secondary packaging materials. (10 + 10)

2. (a) What is an SOP? Write a typical SOP for the process of sugar coating of a tablet. (10 + 5)

(b) Write a note on material management in a warehouse.

3. (a) What are the regulations involved in the contract manufacture of pharmaceutical dosage form.

(b) What is Quality Audit? What is the scope of Quality Audit? (5 + 10)

II. Short notes : (6 × 5 = 30)

1. Write a note on applications of computers in a Quality Control laboratory.

2. Why are drugs recalled from the market?

3. What are the benefits derived by Indian drug manufacturing companies on account of globalization.

4. What is the importance of patenting drug products and process.

5. What are the responsibilities of a Quality Control laboratory.

6. What is an 'Orange guide'? What are its components?

September 2008

[KT 330] **Sub. Code : 2866**

M.Pharm. DEGREE EXAMINATION.

First Year

(Regulations 2006)

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262866

Time : Three hours Maximum : 100 marks

Answer ALL questions.

I. Long Essays : (3 × 20 = 60)

1. (a) Discuss in detail the term Good laboratory practices, stressing on the responsibilities of quality control laboratory with regard to protocols and instruments.

(b) What is Recall? Add a note on strategies to be applied with regard to the same to find the level of effectiveness. (10 + 10)

September 2008

2. What is Inprocess quality control? Add a note on its importance. Discuss briefly the various inprocess quality control tests carried out for the following dosage forms.

(a) Liquid orals

(b) Tablets

(c) Capsules.

3. (a) What do you understand by SOP? What is its significance? Discuss the salient features of SOP for a manufacturing process.

(b) Discuss briefly the types of glass containers. Add a note on pharmacopoeial tests for various glass containers. (10 + 10)

II. Short notes : (8 × 5 = 40)

1. Discuss the salient features of environmental protection act.

2. Add a note on regulatory aspects of pharmaceuticals.

3. What do you mean by returned goods? How do you handle returned goods?

4. Discuss briefly the quality control tests for plastics.

5. What is Master formula? What are its components?

6. Discuss the organisation and functions of quality control laboratory.

7. Discuss in detail the sanitation and environmental control around the plant premises.

8. Explain the concepts of auditing with special reference to loan licence.

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