[KD 304] **APRIL 2001**

M.Pharmacy DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All the questions carry equal marks.

1. (a) Give an account of the inprocess quality control tests for (i) Tablet and (ii) Injectables. (13)

(b) Write an essay on the various types of plastic materials used in pharma packaging. Explain the quality control tests for the same. (12)

2. (a) Explain the evolution of the concept of Total Quality Management in Pharma Industry from the simple analytical function of a Quality Control Department. (10)

(b) Explain the salient features of Quality System elements of NABL. (15)

3. (a) What do you mean by Non–clinical testing? Give an account of the key provisions under United States GLP regulations for Non–clinical testing laboratories. (13)

(b) Give a brief account on the procedures for WHO certifications. (12)

4. Give a comparative account on the stability testing for the formulations by the conventional method and as per ICH guidelines. (25)

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NOVEMBER 2001

[KE 304]

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. (a) Give an account on quality system–requirements for ISO 9001 certification.

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

(c) Write notes on premises, location and building requirements for Pharma industry. $(10 + 7\frac{1}{2} + 7\frac{1}{2})$

2. (a) What do you mean by in–process control? What is the need for it? Explain the inprocess control test carried out for sterile preparations.

(b) Explain the protocol to be followed in selection of vendors, receipt, storage and release of raw materials for production.

(c) Write notes on Good warehousing practice. (10 + 8 + 7)

3. (a) Write an essay on the types of glass containers and their quality control.

(b) Explain finished products release protocol and Batch release documents.

(c) What do you mean by returned goods? How will you handle it. $(10 + 7\frac{1}{2} + 7\frac{1}{2})$

4. Write notes on the followings :

(a) Quality review and quality audit.

(b) ICH guidelines for validation of analytical methods.

(c) Explain the followings with respect to NABL

(i) Measurement traceability and

(ii) Calibration. (10 + 8 + 7)

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[KH 304] SEPTEMBER 2002

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. (a) What is Inprocess Quality Control? Mention its importance. What are the inprocess quality control tests carried out for (i) Parenterals and (ii) Capsules.(15)

(b) What do you mean by "returned goods"? What are the legal procedures in handling such returned goods? (10)

2. (a) Name the national and international accreditating agencies for quality system accreditation. Give an account on the evolution of "National Accreditation Board for Testing and Calibration Laboratories". (10)

(b) What do you mean by ISO certification? Explain the salient features of various quality system elements of ISO 9002. (15)

3. (a) Explain the current GMP guidelines for maintenance of Sterile area. (12)

(b) Give an account on the quality control tests for glass containers. (13)

4. Give a detailed account on the validation of analytical procedures as per ICH guideline. (25)

APRIL 2003

[KI 304] Sub. Code : 1024

M Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. (a) Explain briefly the basic difference in the Philosophy of ISO 9000 : 1994 and ISO 9000 : 2000.

(b) Explain the GMP guidelines on selection, training, health, clothing and sanitation requirements of personnel employed in pharmaceutical industries. (10 + 15)

2. Give a detailed account on the inprocess control tests for the following formulations :

(a) tablets

(b) liquid orals. (15 + 10)

3. (a) Explain the various types of closures used. What do you mean by closure liners? Write notes on the types of liners used and the factors to be considered in selecting liners. (15)

(b) Explain the Pharmacopoeial tests for various glass containers. (10)

4. (a) Give an account on the GMP guidelines on good warehousing practice. (8)

(b) How will you respond to a complaint regarding the quality and safety of particular batch of a product? (9)

(c) What are the duties of a study director in carrying out non clinical laboratory study? (8)

OCTOBER 2003

[KJ 304] Sub. Code : 1024

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper IV — QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. (a) What are ISO 9000 series standards? What are the quality elements? (13)

(b) What is process validation and explain different steps of process validation. (12)

2. (a) Explain the concept of TQM. (6)

(b) How stability data is generated according to ICH guideline? (6)

(c) Write a note on auditing. (6)

(d) Explain the significance of Batch production records. (7)

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

(b) Explain the precautions to be taken to maintain the sanitation, environmental control around the plant premises. (7)

(c) Discuss the procedure for registration. (6)

(d) Discuss the concept of procedural manual. (6)

4. (a) Discuss the in process quality controls on sterile dosage forms. (7)

(b) Discuss the restrictions on animal house. (6)

(c) Write a note on good warehousing practice. (6)

(d) Write a note on packaging and labelling controls. (6)

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APRIL 2004

[KK 304] Sub. Code : 1024

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

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 the questions.

SECTION A

Long Essay : (2 × 15 = 30)

1. Discuss the design, construction and maintenance of warehouse. Add a note on ware housing for finished drugs and packaging control.

2. Write in detail in process quality control on solid dosage forms of non-sterile product. Outline the different guidelines with reference to stability testing of formulation.

SECTION B

Short notes : (10 × 5 = 50)

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

4. Give an account of evaluation of complaints.

5. Highlight the procedure of Accreditation (NABL)

6. Write briefly about packaging and labelling control.

7. Write a note on Product Recall with reference to Recall procedure.

8. Point out the ICH guideline followed by Industries while preparation of sterile product.

9. Give a brief notes on ISO 9000.

10. Write the purchase specification for raw materials in industry.

11. What is the need for distribution records in industry?

12. Write notes on various activities at different stages in Total Quality Management.

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AUGUST 2004

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

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

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)

1. Give an account on the types of plastics used for the manufacture of pharmaceutical containers.

2. Explain the ICH guidelines to carryout stability testing.

SECTION B — (10 × 5 = 50 marks)

3. Write notes on sampling and sampling plan.

4. Write notes on the organization and functions of National Accreditation Board for Testing and Calibrating Laboratories. (NABL)

5. Explain the advantages to various stake holders in getting ISO certification.

6. Explain Quality Management principles based on ISO 9001 : 2000.

7. Explain the pharmacopoeial tests for various containers.

8. Discuss the restrictions on animal house.

9. Discuss the procedure for registration.

10. Discuss the concept of procedural manual.

11. What are the legal procedures in handling "returned goods"?

12. What is Inprocess Quality Control?

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