[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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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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March 2009

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

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

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

1. What are the different types of packaging material used in a pharmaceutical industry? Add a note on quality control of secondary packaging materials.

2. Give an account on concept and philosophy of TQM.

3. Write notes on the following:
   a) Quality audit of manufacturing process and facility.
   b) SOP for membrane filtration.
   c) Batch Release Document.

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

1. Write application of computers in quality control laboratory.
2. What is master formula record and write its importance in pharmaceutical industry.
3. When and how pharmaceutical products are recalled from the market?
4. Write a note on regulatory drug analysis.
5. Write the process and importance of patenting.
6. What criterias are considered while locating a pharmaceutical manufacturing facility?
7. What protocols are followed while selecting vendors?
8. Write the salient features of consumer protection act.

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September 2009

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

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

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

1. a) Write a detailed note on concepts and philosophy of ISO – 9000.
   b) How the sanitation and sterile areas are maintained in pharma industry?

2. a) What are methods and equipment involved for dry heat sterilization?
   b) How the quality control of packing material is achieved?
   c) What are the tests to be performed for assuring quality of glass?

3. a) Write notes on purchase specifications for raw materials.
   b) Give an account on standard operating procedures.
   c) Write about the training of personnel.

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

1. What are various types of plastics used as packing materials?
2. Discuss concepts of Good Laboratory practice with suitable examples.
3. Explain the concepts of auditing with special reference to loan license.
4. How the recovered goods are handled?
5. Write a note on recent amendments in drug and cosmetics act.
6. What are the advantages and disadvantages with the globalization of drug industry?
7. Describe the regulatory aspects of pharmaceuticals and bulk drug manufacturing.
8. Give an account on loan licensing auditing.

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March 2010

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

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

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

1. a) Write a detailed note on concepts and philosophy of Total quality management.
   b) Give a detailed account on location and building requirements for pharma industry.

2. a) What do you understand by SOP? What are its salient features for a manufacturing process?
   b) Explain the significances of SOP.
   c) Write about the training of personnel.

3. What are the protocols to be followed in selecting vendors? Add a note on Purchase, receipt, storage, and release of raw materials.

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

1. Discuss concepts of good laboratory practice with suitable examples.
2. Give an account on quality audits of manufacturing processes and facilities.
3. Give an account on key provisions under united states GLP regulations for non-clinical testing laboratory.
4. Discuss the salient features of environmental protection act.
5. What is master formula? What are its components?
6. Describe the regulatory aspects of pharmaceuticals and bulk drug manufacturing.
7. Give an account of good ware housing practice.
8. Give an account on standard operating procedures for compression.

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September 2010

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

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

(Candidates admitted from 2006-2007 onwards)

FIRST YEAR

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

1. a) Explain Quality control for secondary packaging materials for Pharmaceuticals.
   b) Explain different types of Glass containers and their Quality control test.

2. a) Write a note on concepts and philosophy of GMP.
   b) What are the standard operating procedures for cleaning, drying and sterilization?

3. a) What are the necessary conditions to be fulfilled for purchase specification and maintenance of stocks for raw materials?
   b) How are sanitations and sterile area are maintained in pharmaceuticals premises?

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

1. What are the applications of computers in Quality control laboratory?
2. What are the procedures required for evaluation of complaints and recall of distributed finished products?
3. Give the Quality control test of strip and blister packing materials.
4. Write a short note on Consumer Protection Act.
5. What are the various types of Plastics used in packing materials?
6. What are the purchase specifications to be followed for raw materials?
7. Give an account on Loan Licensing Auditing.
8. Discuss in detail the Sanitation and Environmental control around the plant premises.

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MAY 2011

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

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

(Candidates admitted from 2006-2007 onwards)

FIRST YEAR

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

1. a) Write the Concepts and Philosophy of TQM. **(7)**
   b) Write about the Master formula records. **(7)**
   c) Write note on manufacturing documents. **(6)**
2. a) List out the various responsibilities of qualified personnel in a manufacturing unit. **(6)**
   b) Write in detail about location and building requirements for Pharma industry. **(6)**
   c) Write brief note on Organization and personnel. **(8)**
3. a) Classify packaging materials and tests to ensure the quality of secondary packaging materials? **(14)**
   b) Write briefly on loan license auditing. **(6)**

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

1. Write the significance of Standard Operating Procedures.
2. Write a note on Good Warehousing Practices.
3. Quality Control Documentation and its importance.
4. How can you prevent mix up and cross contamination during production?
5. Explain the pharmacopoeial tests for various glass containers.
6. Write short notes on ISO-9000.
7. How the sanitation and sterile areas are maintained in pharma industry?
8. How can you dispose the scrap?

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