MAY 2011

[KY 355] **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION

(Regulations 2010)
(Candidates admitted from 2010-2011 onwards)

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

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

Answer All questions

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

1. Write about the training of personnel.
2. Give a detailed account on location and building requirements for pharma industry.
3. What are the protocols to be followed in selecting vendors? Add a note on purchase, storage, and release of raw materials.
4. Describe the components of master formula and batch formula records.
5. Explain different types of Glass containers and their Quality control tests.
6. Quality audit of manufacturing process and facility.

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

1. Therapeutic Goods Administration (TGA).
2. Total Quality Management (TQM).
3. Good Laboratory Practice (GLP).
4. Good Manufacturing Practice (GMP).
5. Scrap disposal.
6. Globalization of Drug Industry.
7. Hygiene.
8. Loan License Auditing.

****

October 2011

[KZ 355] **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : 3 hours **Maximum : 100 marks**
(180 Min)

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. Discuss on containers and closures used in pharmaceutical industry and discuss their quality assuring test.	17	40	20
2. a) Discuss on standard operating procedure and write its significance for a manufacturing process.	17	40	20
b) Concept and philosophy of Good Manufacturing Practice			
II. Write notes on :			
1. Write the significance of environmental protection act	4	10	6
2. Write the process for patent and discuss its significance	4	10	6
3. Concept of loan license auditing	4	10	6
4. Master and Batch formula records	4	10	6
5. Scrap disposal procedure	4	10	6
6. How do you design sterile area for pharmaceutical industry?	4	10	6
7. Write on selection of vendors	4	10	6
8. When pharmaceutical products are recalled from market	4	10	6
9. Write notes on regulatory drug analysis	4	10	6
10. Good warehousing practice	4	10	6

****

[LA 355] **MAY 2012** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code: 262916

Time: 3 hours **Maximum: 100 marks**

(180 Min)

Answer ALL questions in the same order.

I. Elaborate on:	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. Explain the concepts and philosophy of TQM.	17	40	20
2. Write detailed note on selection, purchase, sterilisation and maintenance of equipment.	17	40	20
II. Write notes on:			
1. Batch formula record.	4	10	6
2. Control of raw materials.	4	10	6
3. SOP for sterilisation.	4	10	6
4. GLP.	4	10	6
5. Warehousing management.	4	10	6
6. Handling of returned goods.	4	10	6
7. Evaluation of complaints.	4	10	6
8. Environmental protection act.	4	10	6
9. Globalisation of Drugs Industry.	4	10	6
10. Regulatory affairs.	4	10	6

****

[LB 355] **NOVEMBER 2012** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMS

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : 3 hours **Maximum : 100 marks**

(180 Min)

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. Write in detailed note on a. Food and drug administration (FDA) b. Therapeutic Goods administration (TQM).	17	40	20
2. a) Discuss on standard operating procedure and write its significance for manufacturing process. b) Concept and philosophy of Good Manufacturing Practice.	17	40	20

II. Write Notes on :

1. List out different types of packaging materials used in pharma industry.	4	10	6
2. Write the application of computers in quality control laboratory.	4	10	6
3. Discuss on regulatory drug analysis.	4	10	6
4. Write the significance of environmental protection act.	4	10	6
5. Write the process for patent and discuss its significance.	4	10	6
6. Write the concept of loan license auditing.	4	10	6
7. Master and Batch formula records.	4	10	6
8. Regulatory aspects on bulk drug manufacturing.	4	10	6
9. Good laboratory practice.	4	10	6
10. How do you design sterile area for pharmaceutical industry?	4	10	6

[LC 355] **APRIL 2013** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMS

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : 3 hours **Maximum : 100 marks**

I. Elaborate on : **(2x20=40)**

1. Write note on purchase specification for raw materials and discuss regulatory aspects on bulk drug manufacturing.
2. Outline the packaging material used in pharmaceutical industry and explain the different types of quality assuring test for glass and plastic container.

II. Write notes on : **(10x6=60)**

1. Food and Drug Administration (FDA).
2. Therapeutic Goods Administration (TGA).
3. Standard operating procedure for compression and coating.
4. Good warehousing practice.
5. Scrap disposal procedure.
6. Describe manufacturing documents.
7. Write on selection of vendors.
8. Concept of loan license auditing.
9. Regulatory aspect control on animal house.
10. Describe Master formula records.

****

[LD 355] **OCTOBER 2013** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATIONS

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time: Three Hours **Maximum: 100 marks**

Answer ALL questions in the same order.

I. Elaborate on : **(2 x 20 = 40)**

1. Discuss in detailed about globalisation of drug industry, introduction to export of drugs and import policy.

2. Write the different types of closures and closure liners. Explain QC of packaging material and filling equipment.

II. Write notes on : **(10 x 6 = 60)**

1. Orange guide
2. Master Formula
3. Controls on Raw materials
4. SOP for drying
5. Quality control of packaging material
6. Batch release document.
7. Handling of returned goods
8. Waste disposal
9. Concepts of auditing
10. FDA.

****

[LE 355] **APRIL 2014** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMS
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : 3 hours **Maximum : 100 marks**

I. Elaborate on : **(2x20=40)**

1. Write detailed notes on concepts and philosophy of orange guide.
2. Discuss in detailed about standard operating procedures for various operations.

II. Write notes on : **(10x6=60)**

1. Maintenance and Sanitations of premises.
2. Purchase specifications for equipments.
3. Batch Formula Records.
4. Distribution of records.
5. Regulatory drug analysis.
6. Loan License Auditing.
7. Complaints and Recalls
8. Scrap disposal procedure and records.
9. Environmental protection act.
10. TGA.

****

[LF 355] **OCTOBER 2014** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

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

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the concepts and philosophy of ISO-9000.

2. Discuss the different types of closures and closure liners. Explain QC of packaging material and filling equipment.

II. Write notes on: **(10 x 6 = 60)**

1. QC laboratory
2. Master formula record
3. Control of contamination
4. Selection of vendors
5. Good warehousing practice
6. Quality audits
7. Recall procedure
8. Waste disposal
9. Recent amendments of drugs and cosmetic act
10. Import policy

****

[LG 355] **APRIL 2015** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH V – PHARMACEUTICAL ANALYSIS

PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time: Three Hours **Maximum: 100 marks**

Answer ALL questions

I. Elaborate on : **(2 x 20 = 40)**

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

2. 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.

II. Write notes on : **(10 x 6 = 60)**

1. Good Laboratory Practice (GLP).

2. Quality audits of manufacturing processes.

3. Consumer Protection Act.

4. Quality review.

5. Handling of returned goods.

6. Scrap disposal procedure and records.

7. Sterilization area.

8. Concepts and Philosophy of TQM.

9. Patent regimen.

10. Controls on animal house.

****

[LH 355] **OCTOBER 2015** **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

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

I. Elaborate on: **(2 x 20 = 40)**

1. Write detailed note on selection, purchase, sterilization and Maintenance of equipment.

2. Discuss on containers and closures used in pharmaceutical industry and discuss their quality assuring test.

II. Write notes on: **(10 x 6 = 60)**

1. Regulatory affairs.
2. Warehousing management.
3. Good laboratory practice.
4. Regulatory aspect control on animal house.
5. ISO-9000.
6. Quality review.
7. Control of contamination.
8. Application of computers in quality control laboratory.
9. Concept of loan license auditing.
10. Handling of returned goods.

****

[LI 355] APRIL 2016 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Describe the details of standard operating for procedure for compression and coating of pharmaceutical dosage form.
   b) Write a note on the spectrum and functions of regulatory affairs.

2. a) Write in detail concepts and philosophy of TQM.
   b) Describe the procedure for getting loan license and auditing.

II. Write notes on: **(10 x 6 = 60)**

1. Patent filing procedure.
2. Import procedures for pharmaceutical products.
3. Role of Medicines and Healthcare products Regulatory Agency (MHRA).
4. Pharmaceutical waste management guidelines for listed wastes.
5. Classification and Handling Procedures of Returned goods.
6. Types and description of auditing.
7. Tests assuring quality of glass.
8. Design of premises.
9. Administration of the Drugs and Cosmetics Act 1940 and relevant rules.
10. Objectives & Salient features of Consumer Protection Act.

****

[LJ 355] OCTOBER 2016 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Write in detail about the Quality control procedures for finished product.

   b) Impact of Globalization in Indian Pharmaceutical Industry.

2. a) Explain the packaging and labeling controls for the plastics used in pharmaceutical manufacturing and its modification by drugs.

   b) Write a note on good warehousing practice.

II. Write notes on: **(10 x 6 = 60)**

1. Principles of GMP.
2. Hygiene control in organization.
3. Purchase specifications for raw materials.
4. Quality audits of manufacturing processes.
5. Standard operating procedure for drying.
6. Quality control protocols for animal house.
7. Steps in evaluation of complaints.
8. General principles of recall procedures.
9. Regulatory issues in pharmaceutical drug manufacturing.
10. Objectives and functions of the purchase committee.

****

[LK 355] MAY 2017 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Explain in detail the regulatory affairs of UKMCA.

   b) Give a detailed account on location and building requirements for pharma industry.

2. Discuss the different types of closures and closure liners. Explain quality control of packaging material and filling equipment.

II. Write notes on: **(10 x 6 = 60)**

1. What is quality audit? Explain the quality auditing of laboratories.
2. Controls on animal house.
3. Sterlisation of area.
4. When pharmaceutical products are recalled from market?
5. Good Laboratory Practice (GLP).
6. Write the note on certification.
7. Write the concept of loan license auditing.
8. Write the significance of environmental protection act.
9. Import policy.
10. Therapeutic Goods Administration (TGA).

****

[LL 355] OCTOBER 2017 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) How the quality control of packing material is achieved?
   b) What are the tests to be performed for assuring quality of glass?
   c) Write a detailed note on concepts and philosophy of Total Quality Management.

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.

II. Write notes on: **(10 x 6 = 60)**

1. Briefly write the quality review.
2. Write the importance of patenting drug products and process.
3. Sop for coating.
4. Consumer protection act.
5. Role of master formula in record maintenance.
6. Give an account on product recall with reference related records and documents.
7. What are the responsibilities of a Quality Control Laboratory?
8. List out the various responsibilities of qualified personnel in a manufacturing unit.
9. WHO certification.
10. Discuss the salient features of environmental protection act.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LM 355] MAY 2018 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Write in detail about certification of World Health Organisation.
   b) Explain the Import policy and Export of drugs.

2. a) Discuss in detail the term "Good laboratory practices" give stress on the responsibilities of quality control laboratory with regard to protocols and instruments.
   b) Write in brief about finished product release.

II. Write notes on: **(10 x 6 = 60)**

1. Waste disposal.
2. Batch release document.
3. Methods and equipment involved for Dry Heat Sterilization.
4. SOP for membrane filtration.
5. Explain the concepts of TQM.
6. Quality control for secondary packaging materials.
7. Location and building requirements for Pharma Industry.
8. Training of personnel.
9. Quality control of filling equipment.
10. Write a note on maintenance of stores.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LP 355] OCTOBER 2019 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the following term:
   a) Line clearance.
   b) Reconciliation of labels.
   c) Bubble packs.
   d) Permeation and Leaching.

2. a) Write a detailed note on recent amendments to drugs and cosmetic act and consumer protection.
   b) Give a detailed account on plan layout and construction of Pharma industry.

II. Write notes on: **(10 x 6 = 60)**

1. What is TQM? Explain in detail.
2. Quality audit.
3. Master formula record.
4. Write note on selection of vendors.
5. Write about the material and management in warehousing.
6. Evaluation of complaints.
7. Disposal of waste procedure and records.
8. Regulatory aspects of drug analysis.
9. Write the process of patent and discuss its significance.
10. SOP of sterilization.

****