Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602T)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE / DRUG REGULATORY AFFAIRS)
(2014 REGULATION)

Wednesday, May 20, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

- **Answer ALL Questions.**
- **Use of scientific calculator is allowed**
- **Draw neatly labeled diagram wherever necessary**

1. Write in detail about location, design, plant layout, and construction of a GMP approved pharmaceutical manufacturing facility.

(10 marks)

2. What are the points to be considered for equipment selection, purchase specification and preventive maintenance of equipment used in the pharmaceutical manufacturing?

(10 marks)

3. Write the significance of in-process quality control tests. Explain in-process quality control tests for sterile dosage form.

(10 marks)

4. Write in detail about the line clearance, reconciliation of labels, labelling and packaging operations in pharmaceutical industry.

(10 marks)

5. Explain in detail about the water system validation in pharmaceutical industry.

(10 marks)

6. Explain in detail about control on animal house in non-clinical testing laboratory.

(10 marks)

7. Systolic blood pressure values (X) of 4 occupations are given, Determine if there is significant difference in mean blood pressure of 4 groups in order to access the role of occupation in causation of BP. Justify.

Officers (X1)	Clerks (X2)	Lab technicians (X3)	Attendants (X4)
125	120	120	118
130	122	115	120
135	115	115	118
120	110	130	120
115	125	120	120
120	122	125	115
130	120	122	125
135	120	115	125
140	126	126	120
135	120	118	115

(10 marks)

8. What is the importance of documents in pharmaceutical industry and write in detail about components of batch manufacturing record and master formula record.

(10 marks)

9A. Write about routine controls on instruments in quality control laboratory.

9B. Write note on handling of the complaint in pharmaceutical industry.

(5+5 = 10 marks)

10A. Define SOP and enlist the components of SOP.

10B. Write about importance of hygiene in pharmaceutical plant.

(5+5 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – JULY 2015

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE / DRUG REGULATORY AFFAIRS)
(2014 REGULATION)

Wednesday, July 22, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

- **Answer ALL Questions.**
- **Use of scientific calculator is allowed**
- **Draw neatly labeled diagram wherever necessary**

1. Write in detail about the personnel responsibilities, training, and hygiene while working in GMP approved pharmaceutical manufacturing plant.

(10 marks)

2. Write in detail about ISO 9000.

(10 marks)

3. Write the significance of in-process quality control tests. Explain in-process quality control tests for non-sterile dosage form.

(10 marks)

4. What is Quality Audit? What are its objectives? Explain different types of quality audit in details.

(10 marks)

5. Write in detail about the waste disposal procedure and records thereof in pharmaceutical industry.

(10 marks)

6. Explain in detail about the manufacturing process validation.

(10 marks)

7. A study was conducted with Amlodipine 25 mg tablets on hypertensive patients. The patients were divided into two groups. One group received drug and other received placebo. After 12 weeks the blood pressure was measured and the difference between before the start of the study and after 12 weeks of treatment is tabulated below. Is the decrease in blood pressure is influenced by the drug? Justify.

Amlodipine 25mg group (mmHg)	Placebo group(mmHg)
50	10
40	30
30	20
30	40
20	20
60	10
20	30
30	40
30	30
60	20
70	20
50	30
30	-

(10 marks)

8. Describe in detail about the recall procedures.

(10 marks)

9A. Write a note on good Warehouse practice.

9B. Write a note on Distribution and distribution record.

(5+5 = 10 marks)

10A. Define validation and explain prospective validation.

10B. Explain about the preparation and storage of reagent in quality control laboratory.

(5+5 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: REGULATORY AFFAIRS (PQA 603T)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)
(2014 REGULATION)

Monday, May 25, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ Answer ALL questions.

1. Classify and explain the impurities as per ICH Q3A (R2) guidelines.

(10 marks)

2. What is meant by "Protection of Undisclosed Information"? Write a note on "Confidentiality Agreement".

(10 marks)

3. Write a note on major regulatory submission requirements by ANVISA and PICS for pharmaceutical drug products and drug substances.

(10 marks)

4. Write a note on evaluation of Q4B process as per ICH.

(10 marks)

5. Write a note on contents of site master file as per European commission.

(10 marks)

6. Enlist inventions that are patentable and non-patentable according to Indian Patents Act 1970. Write a note on provisional application and complete specification.

(10 marks)

7. Differentiate between stability testing of drug substances and drug products as per ICH Q1A (R2).

(10 marks)

8. Explain the requirements of the bar code rule and responsible authorities subject to its implementation.

(10 marks)

9. **Write short notes on:**

9A. Explain methodology for classifying a drug substance and determining the dissolution characteristics of a drug product

9B. Write a brief note on module 4 and module 5 of e-CTD.

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Explain in detail current GMP guidance for combination products as per FDA.

10B. Briefly explain patent cooperation treaty.

(5+5 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

(2014 REGULATION)

Wednesday, May 27, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1A. Explain liquid - liquid extraction technique for the analysis of drugs in biological fluids. List its advantages over protein precipitation technique .

1B. Explain the crystal properties and polymorphism in preformulation studies.

(5+5 = 10 marks)

2. Explain in detail the bacterial endotoxin test. Discuss difference between microbial limit test and sterility testing.

(10 marks)

3. Explain the importance of solubility in preformulation studies .

(10 marks)

4. Enlist various methods for determination of water content in pharmaceutical articles. Explain in brief the principle, apparatus used and the testing procedure for the direct titrimetric method. How does this method differ from the residual titration method?

(10 marks)

5A. What is the importance of uniformity of content for the single dose tablets and discuss the same in detail.

5B. Write a note on shelf life estimation by accelerated stability testing.

(5+5 = 10 marks)

6. Explain in detail about finger printing using spectroscopic method.

(10 marks)

7. List the stability guidelines as per ICH and explain in detail about Q1D.

(10 marks)

8A. Explain the construction and any two advantages and disadvantages of dissolution apparatus 1 USP (Basket).

8B. Explain the procedure and acceptance criteria for dissolution testing of immediate release dosage forms.

(5+5 = 10 marks)

9. **Write short notes on:**

9A. IVIVC and levels of correlation

9B. Reference electrodes in potentiometry

(5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. Hydrolytic resistance test for evaluation of glass containers

10B. Instrumentation requirements for thermogravimetry

(5 marks × 2 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – JULY 2015

SUBJECT: REGULATORY AFFAIRS (PQA 603T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

(2014 REGULATION)

Monday, July 27, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ **Answer ALL questions.**

1. Discuss Copyrights, Trademarks and Trade secrets in detail. (10 marks)

2. Explain various stages of filing a patent application in India. (10 marks)

3. Write a note on quantification of impurities as per ICH Q3A (R2) guidelines. (10 marks)

4. Explain in detail setting of dissolution specifications for a new chemical entity in IR formulations as per FDA guidance document. (10 marks)

5. Explain the decision flow chart for stability testing of drug products. (10 marks)

6. Explain contents in module five folder of clinical study reports of e-CTD submission to FDA. (10 marks)

7. Explain the changes to an approved NDA or ANDA with respect to IR formulation. (10 marks)

8. Explain the quality risk management process as per ICH Q9 guidelines. (10 marks)

9. **Write short notes on:**

9A. Explain PAT and its applications in current pharmaceutical development, manufacturing and quality assurance requirements of a pharmaceutical industry.

9B. Write a note on corrective action and preventive action system as per ICH Q10. (5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Explain different methods to document BA-BE studies.

10B. Write a note on steps involved in Pharmacopeial Harmonization. (5+5 = 10 marks)