

MANIPAL UNIVERSITY**M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2009****SUBJECT: REGULATORY ENVIRONMENT AND INTELLECTUAL PROPERTY RIGHTS (PMA 606)****SPECIALIZATION: PHARMACEUTICAL ADMINISTRATION**

Saturday, May 30, 2009

Time: 10.00-13.00 Hrs.

Max. Marks: 100

✍ Answer ALL the questions.

1A. Write short notes on:

- i) Continuation Patent Application
- ii) Divisional Patent Application
- iii) Patent of Addition
- iv) Protection of Undisclosed Information

1B. Enlist various treaties governing IPR and discuss any two in detail. Explain about the activities of WIPO.

(10+10 = 20 marks)

2A. Enlist four ways by which a generic drug manufacturer can file for approval of generic drugs. Discuss importance of Para IV filing applications.

2B. Enlist various components of Intellectual Property Rights. Explain in detail Trademarks and Copyrights with appropriate examples.

(10+(2+4+4) = 20 marks)

3A. Explain in detail patent filing procedure in India.

3B. Explain with a flow chart the INDA review process.

(10+10 = 20 marks)

4A. Which countries legislative efforts had significant impact on pharmaceutical industry and mention in brief any one country's drug laws and legislations?

4B. Write short note on Regulatory Affairs Professional Society.

4C. Discuss Drug Discovery and Development Process.

4D. Discuss in brief the categories of ICH guidelines.

(5×4 = 20 marks)

5A. Define the following terms as per ICH GCP:

- i) Independent Ethics Committee
- ii) Institutional Review Board

5B. Discuss briefly the salient features of Pharmaceutical Policy 2006.

5C. Discuss in brief Process Validation, Cleaning Validation and Packaging Validation.

5D. What is the importance of revising while writing the regulatory documents?

(5×4 = 20 marks)



MANIPAL UNIVERSITY**M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2009****SUBJECT: HUMAN RESOURCE DEVELOPMENT AND AUDITING (PMA 607)****SPECIALIZATION: PHARMACEUTICAL ADMINISTRATION**

Monday, June 01, 2009

Time: 10.00-13.00 Hrs.

Max. Marks: 100

✍ Answer ALL the questions.

- 1A. Discuss the need for Human resource planning and add a note on benefits of Workforce planning.
- 1B. With the help of flow chart explain the Selection process.
(5+5)+10 = 20 marks)
- 2A. Explain the formal evaluation and summative evaluation in training process.
- 2B. What are different stress management techniques? Discuss in detail.
(10+10 = 20 marks)
- 3A. What are different incentive systems? Explain necessity of effective incentive system in organization.
- 3B. Discuss the concept of Human Resource Development Audit. Explain different Human Resource Development Audit methodology and instruments.
(10+10 = 20 marks)
- 4A. Define Communication. Explain the process of Communication.
- 4B. Discuss different Employee assistance programmes with their importance in organization.
(10+10 = 20 marks)
- 5A. Write short notes on:
i) Critical role of human resource.
ii) Different Human Resource Development strategies.
- 5B. Write short notes on:
i) Retraining.
ii) Advantages and disadvantages of traditional and modern methods of Performance appraisal.
(5×2)+(5×2) = 20 marks)



Department of Pharmacy Management

Manipal College of Pharmaceutical Sciences

M.PHARM PART-I PRACTICAL EXAMINATION—JUNE 2009

Specialization - PHARMACEUTICAL ADMINISTRATION

PMA 608: Comprehensive Practical

MAX. MARKS: 300

DATES: 02, 03 and 04 June, 09

TOTAL TIME: 18 Hrs.

Day 1

- Q.1 SYNOPSIS (1hr) 20 Marks**
- a) Write briefly on laws pertaining to manufacture and sale of drugs in India. 5marks
- b) Briefly explain compulsory license. 5Marks
- c) Write short note on employee safety. 5Marks
- d) Write short note on Objectives of performance appraisal. 5Marks
- Q.2 CASE STUDY (ENCLOSED) (2 Hrs) 40 Marks**
- Consumers and citizens

- Q.3 GROUP DISCUSSION / DEBATE / EXTEMPORE (3hrs) 40 Marks**
- Topic:** Impact of recession on Indian Pharma Exports

Day 2

- Q.4 DISEASE MANAGEMENT PRESENTATION (4 hrs) 75 Marks**
- Present SOP of given disease submit the handouts of presentation

- Q.5 VIVA VOCE (2 hrs) (To be continued on Day 3) 50 Marks**

Day 3

- Q.5 VIVA VOCE (2 hrs) (Continued from Day 2)**
- Q.6 DETAILING PRESENTATION (4 hrs) 75 Marks**
- Detail the given drug and submit the outline