

MANIPAL UNIVERSITY

M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: REGULATORY ENVIRONMENT AND INTELLECTUAL PROPERTY RIGHTS (PMA 606)
(SPECIALIZATION: PHARMACEUTICAL ADMINISTRATION)

Friday, May 30, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

✍ Answer ALL the questions.

- 1A. Discuss in brief drugs laws in Australia.
1B. What are the basic functions of Regulatory Affairs? Discuss in brief the objectives of European Society of Regulatory Affairs.
1C. Differentiate Drug Discovery and Drug Development. (10+5+5 = 20 marks)
- 2A. Discuss in detail steps involved in ANDA process.
2B. Classify ICH Guidelines and enlist the ICH Safety guidelines. (10+10 = 20 marks)
- 3A. Briefly mention the historical development of GLP and define GLP as per OECD guidelines. Write short notes on importance of documentation control while preparing regulatory documents.
3B. Discuss in brief European Patent System. (10+10 = 20 marks)
- 4A. Discuss in detail about Trademarks and Protection of Undisclosed information with specific and relevant examples.
4B. Explain distinguishing feature of Indian Patents Act 1970 and highlight Salient features of Indian Patents Act 2005. (10+10 = 20 marks)
- 5A. Discuss in brief various types of Patent Search. Add a note on Revocation of Patents.
5B. Discuss in detail Patent Cooperation Treaty. (10+10 = 20 marks)



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M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: HUMAN RESOURCE DEVELOPMENT AND AUDITING (PMA 607)
(SPECIALIZATION: PHARMACEUTICAL ADMINISTRATION)

Monday, June 02, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

✍ Answer ALL the questions.

- 1A. Explain in detail the steps involved in developing and conducting a training programme.
1B. Why stress management is essential for employees? Enlist and discuss different stress management techniques.
(10+10 = 20 marks)
- 2A. Job analysis is a basic Human Resource Management Tool. Justify the statement.
2B. Enumerate and explain steps in recruitment process and add note on theories of recruitment.
(10+(5+5) = 20 marks)
- 3A. Explain the role of Motivation and Communication in Employee Relations.
3B. Enumerate accounting concepts and explain any five in detail.
(10+10 = 20 marks)
- 4A. Explain requirements of incentive system to be effective for an organization.
4B. Enumerate and explain different Human Resource Development Audit methodology and instruments.
(10+10 = 20 marks)
- 5A. Write short notes on:
i) Collective Bargaining
ii) Cost reduction and Speed strategy
- 5B. Write short notes on:
i) Problems associated with Performance Appraisal process
ii) Quality of Work Life
(5+5)+(5+5) = 20 marks)

