Question Paper

Exam Date & Time: 03-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL REGULATORY AFFAIRS)
DATE: 03/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Drugs and Cosmetics [PQA-MRA201T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1)	Write the marketing authorization procedures for drugs in European Union.	(5)
2)	Write the regulatory consideration for manufacturing and distribution of cosmetics in Japan.	(5)
3)	Write briefly the EDQM inspection programme for Compliance of European Pharmacopoeia (CEP) application.	(5)
4)	Write the marketing authorization requirement for drugs in Russia.	(5)
5)	Write the content and format for Certificate of Pharmaceutical Product.	(5)
6)	Which are the documents required for the EAC declaration and state registration of Cosmetics in CIS countries.	(5)
7)	Write the marketing authorization procedure for drugs in Saudi Arabia.	(5)
8)	Discuss in detail organization structure and functions of FDA.	(5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9)	Write the importance of purple book.	(2)

A)

B)	Write a note on Orphan Drug Designation program.	(2)
C)	Write a note on FDA's role in a recall of cosmetics in US market.	(2)
D)	What are the contents in IMPD?	(2)
E)	What is type II variation? Give two example for the same.	(2)

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