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.

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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Time: 05-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: 05/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Herbal and Biologicals [PQA-MRA202T]

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

a

Answer all the questions.

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

1) Discuss the process development requirements for biologics as per USFDA. (5)

2) Discuss the difference between "generic drug" and "biosimilar drug". (5)

3) Explain the quality and safety requirements for herbal drugs necessitated by WHO. (5)

4) What are the "competent authorities" and "types of manufacturing licenses" for biologics approval in India? (5)

5) Briefly discuss the principles of development of similar biologics as per CDSCO. (5)

6) Explain the quality attributes in development and manufacturing process of biologics in EU. (5)

7) Discuss the development and registration process of vaccine in India. (5)

8) Discuss the labelling standards for blood and blood components as per US regulations. (5)

b

Answer all the questions.

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

9) What are the types of 510k applications? (2)

A)

Sudhan M.

B) What are "biological contaminants" in herbal drugs?

C) Define "Specification". Enlist any four specifications for biologics as per EU.

D) Write any two strategic goals of International Haemovigilance Network (IHN). (2

E) What is VAERS? (2)

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Time: 07-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: 07/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Medical Devices [PQA-MRA203T]

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

a

Answer all the questions.

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

1) Enlist the general essential principles for safety and performance applicable to all medical devices including IVD medical devices as per GHTF guidelines. (5)

2) What are the exemption rules for not reporting the Adverse event with examples as per GHTF guidance document? (5)

3) Mention in detail the contents of STED document for IVDs as mentioned in GHTF (5)

4) Classify medical software as per IMDRF with appropriate examples. (5)

5) List ASEAN countries and name the regulatory bodies and acts governing Medical devices in each of them. (5)

6) Classify SaMD on basis of risk in the information provided by SaMD to decide on treatment and write in brief the categorization principles of Software as Medical device (SaMD). (5)

7) Write an note on CE marking as per EU directives. (5)

8) Write the active medical devices approval process as per EU. (5)

b

Answer all the questions.

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

9) Mention the adverse event reporting timeline for medical devices as per ASEAN directives. (2)

A)

B) Define medical devices and IVDs with examples.

C) Explain the types of 510(k) Submissions as per USFDA.

D) Write a short note on Medical device approval procedure in Singapore. (2)

E) Classify non-invasive medical devices based on risk and intended use with suitable example. (2)

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Time: 09-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: 09/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Food and Nutraceuticals [PQA-MRA204T]

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

a

Answer all the questions.

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

1) Explain the ambiguity of nutraceutical nomenclature. (5)

2) Write a note on the process of WHO guideline development. (5)

3) Write a note on food equipment certification by NSF. (5)

4) Write a note on "Sampling Procedure" by food safety officers as per FSSA. (5)

5) Write a note on NSF certification. (5)

6) Write a note on dietary supplement labelling requirements as per USFDA. (5)

7) Explain the types of Dietary Reference Values in Europe in brief. (5)

8) Write the methods for deterring the nutritional requirements. (5)

b

Answer all the questions.

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

9) What is SWIFT? (2)

A)

B) What is fortification of food as per FSSA? (2)

C) What are the compliance dates for dietary supplement GMP rules in US?

D) Name any two minerals which have a significant difference in recommended allowance in India and European Union? Why?

E) Name any four functions of US food GMP inspector.

(2)

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