MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: PHARMACEUTICAL REGULATIONS (PRA 601T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Thursday, May 18, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	Briefly discuss various toxicity studies for non-clinical testing.	(10)
2)	Discuss content and format of an Investigational New Drug application.	(10)
3)	Briefly discuss various modules of Common Technical Document.	(10)
4)	Discuss the Hatch-Waxman Act and its outcome. Discuss the types of certifications under ANDA.	(10)
5)	Discuss the orphan drug development program.	(10)
6)	Write briefly on the information required in a RFD (Request For Designation) submission, and discuss the guidance document "How to write a RFD".	(10)
7)	Discuss the guidance document on Best Pharmaceuticals for Children Act.	(10)
8)	Explain drug import licensing procedure and post approval regulations in India.	(10)

Write short notes:

9A)	Regulatory bodies and types of applications for drug regulation in the following countries (i) U.S.A. (ii) E.U. (iii) Canada (iv) Japan (v) India.	(5)
9B)	Requirements for an Abbreviated New Drug Application designation.	(5)

Write briefly on the following:

10A)	Generic drugs and Medical devices regulations in India.	(5)
10B)	Differences in centralized procedure and decentralized procedure for drug registration process in EU.	(5)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: PHARMACEUTICAL PATENT, IPR AND REGULATIONS (PRA 602T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Tuesday, May 23, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	Describe Copyrights, including derivative rights and rights of translation. Add a note on Tradermarks and types of trademarks.	(10)
2)	What are the steps involved in filing for a patent in India. Explain each step.	(10)
3)	What is meant by Tradesecret? How does a Tradesecret benefit business entity? Discuss with relevant examples.	(10)
4)	What is non-disclosure agreement (NDA)? Explain provisions of NDA.	(10)
5)	Discuss types of patent infringement with relevant pharmaceutical examples.	(10)
6)	Explain Patent Cooperation Treaty with the help of a schematic diagram.	(10)
7)	How Patents are useful as a business tool for an industry? Write the criteria required to get a patent granted in India.	(10)
8)	What points are important while drafting a patent claim? Explain whether claim should be broad or narrow.	(10)
9)	What is meant by Licensing? What various forms of licensing exist in pharmaceutical industry?	(10)
10)	**Write short notes on:** i) Provisional and Complete Specification. ii) Compulsory Licensing.	(10)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Thursday, May 25, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	Describe the procedure that need to be written and followed by IRB.	(10)
2)	Discuss in detail about: i) Sources of bias in clinical trials. ii) Phases of clinical trials.	(10)
3)	What are the strategies that needs to be adopted to minimize the amount of blood drawn from pediatric populations? Explain the term ADR.	(10)
4)	What is the use of dose-response information in choosing doses? Discuss in detail about data backup and storage.	(10)
5)	Explain the regulatory requirement in India with regard to contents of a bioequivalence study report. Role of sponsor for electronic trial data handling.	(10)
6)	Discuss about FDA clinical investigator inspections in foreign countries.	(10)
7)	Discuss about implications of data protection for staff and participants.	(10)
8)	Discuss the steps involved in volunteer recruitment process.	(10)

Write short notes on:

9A)	Biodegradation tests for medical devices.	(5)
9B)	Re-evaluation of medical devices.	(5)

Write briefly on the following:

10A)	Applications of IVIVC.	(5)
10B)	Need for clinical trial site management.	(5)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: QUALITY, SAFETY AND EFFICACY REGULATIONS (PRA 604T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Saturday, May 27, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	What is matrixing as per ICH Q1D guidelines? Explain the design factors and design considerations for the same with the help of an example.	(10)
2)	Differentiate between 'USFDA draft guidelines for stability testing' and ICH Q1A (R2).	(10)
3)	Discuss the specifications for biotechnological/biological products as per ICH Q6B.	(10)
4)	Write a note on good case management practices.	(10)
5)	What are the phases of human ventricular action potential? Explain its effect on ventricular repolarization delay.	(10)
6)	Explain Q4B annex for extractable volume for parenteral preparation.	(10)
7)	Define intrinsic dissolution, test preparation and procedure as per USP.	(10)
8)	Define calibration and write about types of calibration for dissolution apparatus as per USP.	(10)

Write short notes on:

9A)	Potential application for quality risk management as per ICH Q9.	(5)
9B)	Pharmacovogilance plan.	(5)

Write briefly on the following:

10A)	The objectives and scope of ICH S4 guidelines.	(5)
10B)	Steering committee of ICH.	(5)