UKA TARSADIA UNIVERSITY

M.Pharm. (QA) (2nd Semester)

040030203 - Regulatory Affairs & New Drug Application

Duration: 3 Hours Max. Marks: 70.

Instructions:

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.
5. Draw diagrams/figures whenever necessary.

Section-1

Q-1 (A) Do as directed: [07]

I) How many addition of IP available till today and mention its published year.

II) Gives full form of following: ISO, ASTM

III) In the year 1954 and 1985 which act is implemented for drugs regulation in India?

IV) What is aim of consumer protection act and when it was implemented?

V) What is review process time line in ANDA?

VI) What is CFR? What is role of CFR?

VII) Who is responsible for standard quality of product in India?

Q-1 (B) Answer the following in brief: (Any 4) [08]

I) What is DMF? Different types of DMF?

II) What is difference between IND and NDA?

III) Mention name of different six types of guidelines in Europe?

IV) Mention different four schedules as per D & C act? Name the schedule for manufacturing and regulation of herbal drugs?

V) Write a note on Legislation.

VI) Write four major changes in IP 1996 and current version?

Q-2 Answer the following: [10]

A) Describe the structure of CTD.

OR

A) Explain in detail the regulatory procedure for the application of NDA.

B) Write a note on Informed Consent Form (ICF)

OR

B) Discuss in detail and requirement of acute, sub acute toxicological studies.

Q-3 Answer the following in detail. (Any 2) [10]

A) Mention the features of generic product development in Pharmaceutical Industries.

B) Outline the regulatory requirements to carry out clinical trials in India.

C) Give detailed account of Various ICH guidelines for regulation of drugs and drug products?

Section-2

Q-4 (A) Do as directed: [07]

I) Gives full form of following. TGA, MHRA

II) Who is founder of ICH?

III) Which are the drug regulatory bodies in US and Japan?

IV) Name the Indian drug regulatory bodies?

V) In which year Pollution control act implemented?

VI) Which are the latest addition of USP, BP, EP, and JP?

VII) In which year food safety and standard act implemented in India?

Q-4 (B) Answer the following in brief: (Any 4) [08]

I) Which are the five major national legislative was initiated by US for pharmacy?

II) Mention importance of ISI certification agency.

III) Mention importance of Industrial safety & Health policy.

IV) What is aim and objective of Pollution control act?

V) Which are the organizations responsible for product registration in India, US, and EU?

VI) What is objective of Industrial Development & regulation Act?

Q-5 Answer the following: [10]

A) Discuss in brief the function of FDA in regulation of Pharmaceutical Products.

OR

A) Explain in detail the regulatory protocol to file the INDA application.

B) Describe the quorum requirement for the ethical committee meeting in which the study is approved as defined in Schedule Y.

OR

B) Mention the essential features of Monograph of Pharmacopoeia.

Q-6 Answer the following in detail. (Any 2) [10]

A) Write in brief about the importance of ISO certification agency.

B) What do you mean by process qualification? How it is important to Pharmaceutical Industries?

C) Write a note on function of World Health Organisation.