MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

VIII Semester BPharm – End Semester Examinations July 2021

PQA BP804ET: Pharmaceutical Regulatory Sciences (Theory)

Date:09/07/2021 **Duration:** 02:30 to 04:30 PM **Max. Marks:** 50

Q. No.	CO	Attributes	Question	Marks
1	1	Remembering	Which of the following phase of clinical trial uses healthy volunteers to evaluate the safety of a new drug? a. Phase 1 b. Phase 2 c. Phase 3 d. Phase 4	1
2	1	Application	Main objective of the Phase 1 study is to establish a. Efficacy b. Safety c. Safety and Efficacy d. Route of drug administration	1
3	1	Analysis	The ethical and scientific quality standards for designing, conducting, recording and reporting trials that involves participation of human subjects is known as: a. GLP b. GDP c. GMP d. GCP	1
4	1	Synthesis	What is the other name for Hatch Waxman Act? a. Drug price Competition and Patent Term Restoration Act b. Drug Price Competition Act c. Biologics Price Competition and Innovation Act d. Prescription Drug User Fee Act	1
5	1	Evaluation	Under which paragraph certification ANDA is filed if the generic company wishes to enter the market before patent expiry. a. Paragraph I b. Paragraph II c. Paragraph III d. Paragraph IV	1
6	2	Remembering	---------is/are not function(s) of CDSCO. a. Approval of new drug. b. Approval of vaccines c. Approval of blood banks	1

			d. Regulation of tobacco and related products.	
7	2	Application	After submission of IND, the sponsor must wait ----------calendar days before initiating any clinical trial. a. 30 b. 45 c. 60 d. 90	1
8	2	Analysis	Which of the following module is not a part of ANDA submission? a. Module 2 b. Module 3 c. Module 4 d. Module 5	1
9	2	Evaluation	All of the data of level-3 component and composition changes must be filed in Prior Approval Supplement (PAS) except— a. Dissolution data b. In-vivo bioequivalence data c. Accelerated stability data d. Long term stability data	1
10	II 2	Analysis	A manufacturing site of US-FDA approved formulation is being shifted from Ahmedabad to Hyderabad. This change of site must be notified to the regulatory agency in a. Annual report b. Bi-annual report c. Changes Being Effected (CBE) supplement d. Prior Approval Supplement (PAS)	1
11	II 2	Synthesis	Change in the manufacturing process from wet granulation to direct compression of dry powders is considered as a. Level-I change b. Level-II change c. Level-III change d. None of the above	1
12	III 3	Application	The SUGAM portal under CDSCO is used to submit applications for attaining a. Marketing approval b. Clinical trial approval c. Import license d. All the above	1
13	IV 3	Application	Phase-2 clinical trials is for: a. Safety b. Marketing c. Final approval d. Design	1
14	IV 3	Analysis	Expedited review is for a. The proposals presenting more than minimal risk to research participants b. The proposals presenting no more than minimal risk to research participants	1

			c. The proposals presenting no risk to research participants. d. The proposals for educational purposes only	
15	3	Evaluation	Expand the acronym PSUR (with respect to clinical trials) a. Periodic Safety Update Reviews b. Periodic Soft Update Reports c. Purpose Safety Update Reports d. Periodic Safety Update Reports	1
16	3	Synthesis	One of the following is an essential element of informed consent form: a. Benefits b. Approximate number of subjects in study. c. Additional costs to subjects d. Withdrawal criteria	1
17	1	Application	National Regulatory Authorities of which of the following is designated as "Stringent Regulatory Authority" by WHO? a. India b. Brazil c. Cyprus d. Egypt	1
18	1	Analysis	_____ appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. a. Black Box Warning b. Adverse Drug Reaction c. Off label Use d. Preclinical Data	1
19	1	Evaluation	Following is not a law, but an act. a. Labour b. Pharmacy c. Contract d. Criminal	1
20	1	Synthesis	Orange book can also be called as _____ a. Therapeutic Equivalence Book b. Safety and Effectiveness Book c. Approved Drug Product Book d. All nomenclatures can be used	1

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Answer all the questions.

Q. 1 to Q.20 – MCQs – Quiz Section – 2:30 PM to 2:50 PM 20 Marks

Q.21 Explain the Hatch-Waxman Act. How the act balanced the interests of the customers, Innovator Company and the generic drug industry? 5 Marks

Key: Explanation on HW act — 2M.
Correlation of Stakeholder - 3M

Q.22 A formulation of a tablet dosage form was upgraded from the existing formula in the following respect

SN	Component	± %w/w Change
1	Filler	+3%
2	Starch	-2%
3	Lubricant	-1%

Under which category this change should be notified to the regulatory agency. What test documentation is expected by the regulatory agency to approve this change? 5 Marks

Key:
Category of change → VIM
Test documentation → 4M

Q.23 Write a short note on Drug Master File (DMF). 5 Marks

Q.24 Enlist the contents of regulatory dossier to be submitted to Malaysia & Vietnam.

—Answer at end— 5 Marks

Q.25 List the advantages of clinical practice over clinical trials. 5 Marks

Q. 26 Product A – ciprofloxacin hydrochloride tablet containing ciprofloxacin USP – 500 mg, dicalcium phosphate 27mg, lactose 8mg, starch 11mg and magnesium stearate – 3mg. (all per tablet) and showed the following pharmacokinetic values.

C max – 3.80 µg/mL, t max – 1.0 hr and AUC – 563 µg.h/mL

Product B – ciprofloxacin hydrochloride tablet containing ciprofloxacin USP – 500mg, dicalcium phosphate 27mg, sodium starch glycolate 8mg, polyvinyl pyrrolidene 3mg and silicon dioxide 1.3mg. (All per tablet) and showed the following pharmacokinetic values.

C max – 3.95 µg/mL, t max – 1.2 hr and AUC – 648 µg.h/mL

Product C - Norfloxacin capsules containing norfloxacin USP 500mg, talc 10mg and microcrystalline cellulose 26mg. (All per capsule) and showed the following pharmacokinetic values.

C max – 3.51 µg/mL, t max – 1.0 hr and AUC – 626 µg.h/mL

Product D – Ciprofloxacin tablets containing ciprofloxacin 500mg, ethyl cellulose 16mg, titanium dioxide 2.6mg, sodium citrate 22mg (All per tablet) and showed the following pharmacokinetic values.

C max – 6.38 µg/mL, t max – 7.1 hr and AUC – 1524 µg.h/mL.

State which of the products are:

i. Pharmaceutical Equivalents
ii. Pharmaceutical Alternatives
iii. Therapeutic Equivalents.

Justify your selection. 5 Marks

----------xox---------End of question paper-------xox----------

Q.24 Enlist the contents of regulatory dossier to be submitted to Malaysia & Vietnam. 5Marks

Key: Mentioning the format of dossier 1 Mark, contents – 4 Marks

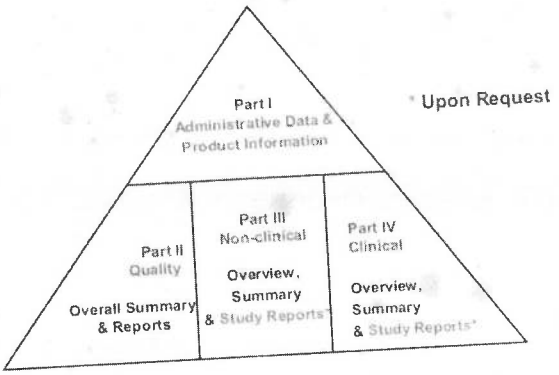
Part I: Table of Content Administrative Information and Prescribing Information

Part II: Quality Document

Part III: Nonclinical Document

Part IV: Clinical Document

ASEAN: Organization of Application Dossier (ACTD)



Q.23 Write a short note on Drug Master File (DMF). 5 Marks

Key:

What is DMF – 1 Mark, Types of DMF with explanation – 4 Marks

- A Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about

- facilities,

- processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

- Submission of a DMF is not required by law or FDA regulation.
- A DMF is submitted solely at the discretion of the holder.
- Information contained in the DMF may be used to support

- an Investigational New Drug Application (IND),

- a New Drug Application (NDA),

- an Abbreviated New Drug Application (ANDA),

- another DMF, an Export Application, or amendments and supplements to any of these.