Seat No.: _____ *Enrolment No._____*

MALIBA PHARMACY COLLEGE
UKA TARSADIA UNIVERSITY
M. Pharm. Semester – II; Internal Examination April 2014 (Mid Sem)
Subject: 040040203 Global Regulatory Requirements & Validation
Date:09/04/2014; Time: 1:30 pm – 4:30 pm Total Marks: 70

Instructions:

- Attempt any **five** questions.
- Make suitable assumption whenever necessary.
- Figures to the right indicate full marks.

Q.1	(a)	Define drug master file (DMF). Enlist the typical contents of a DMF submission. Discuss the different types of DMFs	**08**
	(b)	Explain the needs of submitting a DMF. Discuss the process of review of a DMF by FDA. What are the situations which may lead to closure of an existing DMF?	**06**
Q.2	(a)	Define the following terms: bioequivalence, modified release formulations, open label trials, pharmaceutical equivalents, pharmaceutical alternatives, reference listed product, randomization and supra-bioavailability.	**04**
	(b)	Discuss the situations where bioequivalence studies are not needed. Give appropriate justification in each case.	**05**
	(c)	Discuss the key aspects of enrollment/exclusion of subjects/volunteers in a clinical study. Explain the situations which demand exclusive recruitment of patients.	**05**
Q.3	(a)	Discuss the key aspects of performing a BA/BE study.	**06**
	(b)	Compare the merits and demerits of parallel and cross-over designs. Discuss the acceptance criteria for establishing BE between two products. Include special cases as well.	**05**
	(c)	Write a short note on orange book.	**03**
Q.4	(a)	Describe the toxicological studies required for IND emphasising species, route of administration, dose and dose group.	**06**
	(b)	Explain in detail the sequential information desired for IND filling of a model new drug.	**08**
Q.5	(a)	Give the characteristics of ideal investigator's brochure. Discuss the function and content of clinical investigator's brochure.	**04**
	(b)	Discuss the NDA review process and filling time frame.	**05**
	(c)	Discuss the technical sections to be submitted to FDA before phase 3 clinical trials.	**05**
Q. 6	(a)	Write a note on types of paragraph filling for ANDA submission and explain 30 months stay period	**06**
	(b)	Describe the types of IND	**05**
	(c)	Discuss the provision of Market exclusivity for the first ANDA applicant	**03**