Seat No.:---------- *Enrolment No.:----------*

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M.Pharm. Sem-II Internal Examination 2012

040030203 Regulatory Affairs & New Drug Application

Time: 1:30 to 4:30 p.m. **Max. Marks: 70**

Date: 23/04/2012

Instructions:

- Question no. **1 is compulsory.**
- From Q.2 to Q.7 attempt any **four** questions.
- Figures to the right indicate full marks.

Q.1 **(a)** **Answer the following: (any six)** **06**

1. Write the full form of MHRA and TGA.
2. What do ISO and ASTM stand for?
3. Which is the latest edition of USP-NF?
4. Name the country where TGA and MHRA are located.
5. Define new drug according to FDA.
6. Give NDA review and filing time frame.
7. What is an IND application?
8. What does FSSAI stand for?

(b) **Describe in brief: (any four)** **08**

1. Define 'Biotechnology-derived product' giving examples.
2. What is Treatment IND?
3. Write the conditions for approval of NDA solely based on foreign data.
4. Explain the significance of ISI certification.
5. What is the content of 'General notices' in pharmacopoeia?
6. Write the objective of the Consumer Protection Act.

Q.2	**(a)**	Discuss the content of an investigator's brochure.	**04**
	(b)	Describe the different phases of clinical trials.	**05**
	(c)	Describe the powers and responsibilities of Food safety officer.	**05**
Q.3	**(a)**	What are the functions of food analyst?	**04**
	(b)	Discuss the general provisions of the Industrial Development & Regulation Act.	**05**
	(c)	Write a note on the regulatory aspects for quality and safety of cosmetics.	**05**
Q.4	**(a)**	Write briefly about the drug regulatory agency of India.	**04**
	(b)	Enlist the different types of DMF. Explain any one in detail.	**05**
	(c)	Write briefly about the objectives and organizational structure of USFDA.	**05**
Q.5	**(a)**	Describe the WHO certification scheme.	**04**
	(b)	Write the content of the CMC section of a NDA.	**05**
	(c)	Write the salient features of The Water (Prevention and Control of Pollution) Act.	**05**
Q. 6	**(a)**	Write briefly about the ISO certification system.	**04**
	(b)	Describe the procedure for complaint handling as per Consumer Protection Act.	**05**
	(c)	Differentiate between IND and NDA.	**05**
Q.7	**(a)**	Discuss GMP guidelines for packaging and labeling of API and its intermediates.	**04**
	(b)	What good practices should the personnel follow during manufacture of biotechnology-derived product?	**05**
	(c)	Explain the importance of industrial safety and health.	**05**

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