Seat No.: _____ *Enrolment No._____*

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M.Pharm 2nd Semester Internal Examination April 2012

040040203 / 040120203 Global Regulatory Requirements and Validation

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

Date: 23/04/2012

Instructions:

- **Question 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. Define green book
2. Write full form of DESI.
3. Define new drug according to FDA.
4. Give NDA review and filing time frame.
5. Name the country where USFDA, TGA, MHRA and ANVISA are located.
6. Write the full form of ERP and SAP.
7. What are pharmaceutical equivalents?
8. Explain the significance of cleaning validation.

(b) Explain in brief (any four) **08**

1. Cross-over and replicate cross-over designs
2. Phases of clinical trials
3. Orange book
4. Treatment IND
5. Conditions for approval of NDA solely based on foreign data
6. DMF

Q.2 (a) What is ICH? Describe its composition and objectives. **04**

(b) What are retrospective and concurrent validation? **05**

(c) Write the content of a validation protocol. **05**

Q.3 (a) Describe the steps involved in qualification of a tablet press. **04**

(b) Write a note on USFDA. **05**

(c) What is CTD? Write briefly its content. **05**

Q.4 (a) Write briefly about WHO and its role as a regulatory body. **04**

(b) Describe the procedure for computer system validation. **05**

(c) Explain the process of ERP and write its advantages. **05**

Q.5 (a) Give the characteristics of ideal investigator's brochure. Discuss the function and content of clinical investigator's brochure. **04**

(b) Describe content of form 356h and general requirements with color codes. **05**

(c) Discuss the technical sections to be submitted to FDA before phase 3 clinical trials. **05**

Q. 6	**(a)**	Discuss the cases wherein the steady state clinical studies are considered to be appropriate.	**04**
	(b)	Describe briefly validation of a tablet manufacturing process.	**05**
	(c)	Write a note on IIG.	**05**
Q.7	**(a)**	What are SUPAC guidelines? Name the different SUPAC guidelines.	**04**
	(b)	How can one make a FOIA request?	**05**
	(c)	Discuss therapeutic equivalence evaluation coding system.	**05**

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