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

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M. Pharm. Quality Assurance **1st** Semester Internal Examination December 2013

040030103 Good manufacturing and Good Laboratory Practices

Time: 10:30 a.m. To 1:30 p.m. Max. Marks: **70**

Date: 09/12/2013

Instructions:

- Attempt all questions.
- Figures to the right indicate full marks.

SECTION 1

Q.1.	**Answer in brief:**	**11**
a	What are GMP guidelines? How does compliance to GMP benefit pharma manufacturers?	**3**
	OR	
a	What is the difference between quality assurance and quality control?	**3**
b	What are purchase specifications?	**2**
c	What are CIP and SIP methods?	**2**
d	List out the utilities required in a pharmaceutical manufacturing company.	**2**
e	Write the importance of good documentation.	**2**
Q.2.	**Answer the following:**	**12**
a	Discuss the GMP considerations at the time of selection of site for a manufacturing plant.	**6**
	OR	
a	Describe the facilities to be provided to personnel and discuss the responsibilities of personnel.	**6**
b	Describe the SOP for cleaning operation of a double cone blender.	**6**
	OR	
b	What are SOPs? Discuss their benefits. How are SOPs prepared?	**6**
Q.3.	**Answer in detail: (Any 2)**	**12**
a	Discuss the GMP guidelines for storage, sampling and issue of raw materials.	**6**
b	Describe the good practices followed in manufacturing area.	**6**
c	What are the good practices to be followed for construction, use and maintenance of equipments?	**6**

SECTION 2

Q.4.	**Answer in brief:**	**11**
a	Describe the tests performed on plastic containers used for packing pharmaceuticals.	**3**
	OR	
a	Write the content of distribution records and waste disposal records.	**3**
b	Explain the terms ‘line clearance’ and ‘reconciliation of labels’ in packaging area.	**4**
c	What are specifications? Explain the different types of specifications.	**4**
Q.5.	**Answer the following:**	**12**
a	Discuss the responsibilities of the quality control laboratory.	**6**
	OR	
a	Write the importance of internal quality audits. Describe the steps involved in an audit.	**6**
b	Explain the pharmaceutical complaint handling procedure.	**6**
	OR	
b	Describe the guidelines given in Sch L1 for GLP.	**6**
Q.6.	**Answer in detail: (Any 2)**	**12**
a	Write a note on good warehousing practices.	**6**
b	Discuss the duties of the management and quality assurance unit as per GLP.	**6**
c	Describe the different certification schemes of WHO.	**6**

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