

Seat No.:-----

Enrolment No.:-----

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M. Pharm. (Pharm. Analysis) 2nd Semester Internal Examination 2012

Pharmaceutical Analysis II

Time: 1:30 to 4:30 p.m.

Max. Marks: 70

Date: 21/04/2012

Instructions:

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

- Q.1** (a) Answer the following: (any six) 06
- 1 What is Super critical fluid?
 - 2 Enlist the methods used for quantitative analysis of dosage forms containing antidiabetic drugs.
 - 3 What is isoelectric focusing?
 - 4 Define crude drug.
 - 5 What is tryptic mapping?
 - 6 Define automated systems.
 - 7 What is ultrafiltration?
 - 8 What is MAS?
- (b) Describe in brief: (any four) 08
- 1 How will you calculate acid insoluble ash value?
 - 2 Describe method for determining extractive value of crude drugs.
 - 3 What is the significance of system biocompatibility in peptide mapping?
 - 4 What is counter current chromatography?
 - 5 Explain column switching as a sample preparation technique.
 - 6 Classify analytical techniques used for solid state analysis.
- Q.2** (a) Discuss the role of phenyl isothiocyanate in sequence determination of proteins and peptides. 04
- (b) Explain the principle of size exclusion chromatography and state its applications. 05
- (c) Discuss pre column and post column derivatization methods for amino acid analysis. 05
- Q.3** (a) Differentiate between types of automatic analytical systems. 04
- (b) Explain how ion exchange chromatography aid in analysis of proteins and peptides. Also discuss factors influencing retention in IEC. 05
- (c) Discuss the role of titrimetric methods in analysis of antihypertensive and antihistaminic drugs. 05
- Q.4** (a) Explain the principle of flow injection analysis. 04
- (b) Discuss the role of NMR spectroscopy in solid state analysis with suitable examples. 05
- (c) Discuss the uses and limitations of peptide mapping. 05
- Q.5** (a) Discuss the role of chromatography in identification of plant constituents with suitable examples. 04
- (b) Describe WHO guidelines for quality control of crude drugs. 05
- (c) Define extraction. Describe different techniques of extraction. 05

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Q. 6

- (a) Discuss the role of spectroscopic techniques in quality control of crude drugs. 04
- (b) Discuss the role of isolation techniques in degradation and impurity analysis. 05
- (c) Discuss the significance of solid phase extraction as a sample preparation technique. 05

Q.7

- (a) What are the advantages of SFC over HPLC and GC? Enlist the components of an instrument used for SFC. 04
- (b) Discuss the fundamental theories controlling sample preparation techniques 05
- (c) Explain synthetic carrier ampholytes and immobilized pH gradients in IEF. 05

2. What is line clearance?

3. Define specifications.

4. Write the full forms of cGMP, ICH.

5. What is shelf life?

6. What do you mean by container and closures?

7. What is schedule M?

(b) Describe in brief (any four)

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1. Explain the terms: Quality Assurance and Quality Control.

2. Write the significance of a good documentation system.

3. Explain the significance of GLP.

4. What is vendor verification?

5. Explain the terms: Prospective validation, Revalidation.

Q.1 (a) Describe the good practices to be followed during storage and sampling of raw materials. 04

(b) What points should be considered while constructing a building for pharma manufacturing? 05

(c) Write the responsibilities of the Quality control department. 05

Q.2 (a) Discuss the good manufacturing practices to be followed in the packaging and labeling stage. 04

(b) Write the content of a batch production record. 05

(c) Explain the GMP guidelines for the selection, location and use of equipment in pharma manufacturing. 05

Q.3 (a) What are the responsibilities of the QA unit as per GLP guidelines? 04

(b) Discuss applications of computers in QC laboratory. 05

(c) Describe protocol of stability testing. 05

Q.4 (a) Describe the good practices to be followed with respect to records and reports. 04

(b) Discuss presentation, recording and interpretation of stability data. 05

(c) Describe the minimum animal care facilities required as per GLP. 05

Q.5 (a) Describe the testing frequency and storage conditions for long term and accelerated stability studies of a new drug as per ICH. 04

(b) Describe the different climatic zones as per ICH guideline. What is meant by significant change? 05

(c) Describe GMP requirements for warehousing and distribution. 05