

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

- Q.2 (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.3 (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.4 (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.5 (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.6 (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