

C.U.SHAH UNIVERSITY

Wadhwan City

Subject Code : **5PS02MPA1**

Summer Examination-2014

Date: 27/06/2014

Subject Name: **Modern Pharmaceutical Analysis**Branch/Semester: **M.Pharm/II**

Time: 02:00 To 5:00

Examination: **Regular****Instructions:-**

- (1) Attempt all Questions of both sections in same answer book / Supplementary
- (2) Use of Programmable calculator & any other electronic instrument is prohibited.
- (3) Instructions written on main answer Book are strictly to be obeyed.
- (4) Draw neat diagrams & figures (If necessary) at right places
- (5) Assume suitable & Perfect data if needed

SECTION-I

- Q.1 Write comment on Following 1X7=7
- i. Amino acid mole Percent
 - ii. *Re-test Date*
 - iii. *Shelf life*
 - iv. High risk API
 - v. Pilot batch
 - vi. Supporting Data
 - vii. Interchangeability
- Q.2 (a) Give a brief account on “tryptic mapping”. 5
- (b) Discuss principle and application of Isoelectric focusing technique of electrophoresis. 5
- (c) Write note on Amino acid sequence analysis. 4
- OR**
- (a) Discuss the properties associated with solid at Particulate level. 5
- (b) Write short note on solid state analysis. 5
- (c) What is the effect of impurities on drug stability and its therapeutic action? 4
- Q.3 (a) Explain the importance of pre-formulation studies. 7
- (b) Describe the analytical techniques for pre-formulation studies. 7
- OR**
- (a) Describe thermodynamic properties in Preformulation study. 7
- (b) Describe the US-FDA guidelines in pharmaceutical analysis 7

SECTION-II

- Q.4 Write comment on Following 1X7=7
- I. Process capability index, Cp
 - ii. Automation
 - iii. Segmented flow analysis
 - iv. Parallel Automation Analysis
 - v. Crude Drug
 - vi. Radioactivity
 - vii. Draize test



- Q.5 (a) Discuss bioburden testing of parenteral products. 5
(b) How are the parenteral dosage forms evaluated for sterility testing? 5
(c) Describe in detail bacterial endotoxin testing in parenteral products. 4

OR

- (a) Write Short note on patch test. 5
(b) Define the term 'Cosmetic'. Give a brief account on ingredients used in manufacturing cosmetic formulation, 5
(c) What is Automated Analysis? State its advantages and briefly explain the concept 4
- Q.6 (a) What do you mean by radiopharmaceuticals? Give a brief account on Q.C tests for radiopharmaceuticals 7
(b) Describe application of NIR in physicochemical characterization of solid dosage form. 7

OR

- (a) Enlist various compendia parameter of standardization of herbal drugs and formulations and discuss any two of them in detail. 7
(b) Discuss ICH guidelines Q1A (R2) 7

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