UKA TARSADIA UNIVERSITY

M. Pham (QA) (2 Semester)

040030202 – Modern Pharmaceutical Analysis

Duration : 3 Hours **Max. Marks:70.**

Instruction:

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figure to the right indicates full marks.
5. Draw diagrams/figure whenever necessary.

Section - 1

Q.1 (A) Do as directed: [07]

I) Define residual solvent

II) Describe solid state analysis

III) Define reference standard with example

IV) List out parameter of analytical method validation

V) Classes of product obtained through genetic engineering

VI) Write full description of MALDI/TOF and for what purpose it used

VII) Write hydrolyzed condition for amino acid in amino acid analysis

Q.1 (B) Answer the following in brief: (Any 4) [08]

I) Tryptic mapping

II) Enlist the storage condition for degradation study

III) Enlist the analytical method for biotechnological products

IV) Isolation of impurity

V) Solid state analysis property associated with bulk level

VI) How would you give florescent exposes for degradation of compound as per ICH

Q.2. Answer the following [10]

A) Isoelectric focusing

OR

A) Describe in detail the content of a preformulation report.

B) Ion exchange amino acid analysis

OR

B) Role of NMR in identification of impurity

Q.3 answer the following in detail (Any 2) [10]

A) Drug product degradation study

B) Describe bracketing & matrixing designs for stability testing of new drug substance according to ICH guidelines.

C) Give brief review of analytical methods used in preformulation study.

Section – 2

Q.4 (A) do as directed: [07]

I) Enlist physical characterization of soiled dosage analysis

II) Define the term cosmetic

III) How to check blend homogeneity in solid dosage form

IV) Define Bioburden

V) Sampling techniques in cleaning validation

VI) Enlist the various radiochemical methods of analysis

VII) Enlist the analytical tests for parenteral preparations

Q.4 (B) Answer the following in brief: (Any 4) [08]

I) Evaluation of hair products

II) What is automated analysis? Why automation is required?

III) How XRD used in solid dosage form analysis, with example.

IV) USP particulate matter anlysis

V) Harmonization of testing methods for multicountry submission

VI) Evolution of sunscreen lotion

Q.5 Answer the following : [10]

A) Discuss sterility testing in injectable

OR

A) Discuss quality control of radiopharmaceuticals.

B) Particulate matter test in injectable

OR

B) Describe flow analysis & its application

Q.6 Answer the following in detail. (Any 2) [10]

A) Quality control methods for medicinal plant materials as per WHO

B) Discuss compendia testing of API

C) Describe role of near infred analysis in solid dosage form analysis