Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Modern Pharmaceutical Analysis

Subject Code: 5PS02MPA2 **Branch: M.Pharm (QA)**

Semester: 2 **Date: 06/05/2017** **Time: 02:00 To 05:00** **Marks: 70**

Instructions:

(1) Use of Programmable calculator and any other electronic instrument is prohibited.
(2) Instructions written on main answer book are strictly to be obeyed.
(3) Draw neat diagrams and figures (if necessary) at right places.
(4) Assume suitable data if needed.

SECTION – I

Q-1 **Attempt the Following questions** **(07)**

a.	Write the use of Draize test.	**1**
b.	What is Patch test?	**1**
c.	Name the Parameter for evaluation of crude drug and herbal formulation.	**1**
d.	What are the benefits of automation?	**1**
e.	Write the classification of automatic analyzers.	**1**
f.	Write the advantages of parenteral preparation.	**1**
g.	Write various techniques for separation techniques of solid dosage forms.	**1**

Q-2 **Attempt all questions** **(14)**

(a)	Explain dissolution standards and general method for dissolution test of enteric coated oral dosage form.	**7**
(b)	Write note on sterility testing.	**7**

OR

Q-2 **Attempt all questions** **(14)**

(a)	Write the Quality control methods for medicinal plant materials as per WHO.	**7**
(b)	Discuss quality control of radiopharmaceuticals.	**7**

Q-3 **Attempt all questions** **(14)**

(a)	What is the concept of solubility? Outline any two methods for the determination of solubility of solid in liquid.	**7**
(b)	Describe the role of near infrared analysis in solid dosage form.	**7**

OR

Q-3 **Attempt all questions**

(a)	Outline the IP method for validation of UV spectrophotometer.	**7**
(b)	Write the usefulness of ion exchange chromatography.	**7**

SECTION – II

Q-4		**Attempt the Following questions**	**(07)**
	a.	Why preformulation study is done?	**1**
	b.	What is the wavelength region for NIR spectroscopy?	**1**
	c.	What are the disadvantages of TLC?	**1**
	d.	Write the names of various thermal analytical methods.	**1**
	e.	What are the goals of preformulation study?	**1**
	f.	What are ICH responsibilities?	**1**
	g.	What are the responsibilities of FDA?	**1**
Q-5		**Attempt all questions**	**(14)**
	(a)	Describe the US-FDA guidelines in pharmaceutical analysis.	**7**
	(b)	What is the effect of impurities on drug stability and its therapeutic action?	**7**
		OR	
Q-5		**Attempt all questions**	**(14)**
	(a)	Write a note on isolation and identification of impurities.	**7**
	(b)	Elaborate on quality control of pharmaceuticals.	**7**
Q-6		**Attempt all questions**	**(14)**
	(a)	Enlist different analytical tests for finished parenteral products.	**7**
	(b)	Discuss various stages of pre formulation studies.	**7**
		OR	
Q-6		**Attempt all Questions**	**(14)**
	(a)	Define the term ‘Cosmetic’. Discuss the methods of analysis	**7**
	(b)	What are the regulatory requirements of cosmetic formulations?	**7**