Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Quality Assurance, GMP & Process Validation

Subject Code: 5PS02QGP2 **Branch: M.Pharm (Pharmaceutics)**

Semester: 2 **Date: 09/05/2017** **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 **Define the following terms:** **(07)**

a. Production planning **1**
b. Cross-contamination **1**
c. Documentation **1**
d. Batch Packing Record **1**
e. Batch Processing Record **1**
f. cGMP **1**
g. HVAC **1**

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

(a) Describe the factors affecting the location of a pharmaceutical industry. **7**
(b) Write IPQC test for tablets. **7**

OR

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

(a) Prepare departmental layout with equipment required for liquid orals. **7**
(b) Write in detail on Batch Manufacturing Record with suitable examples. **7**

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

(a) Discuss importance of HVAC facilities for pharmaceutical industry. **7**
(b) What is the importance of production planning? Give methods for inventory control. Using suitable example, explain the production planning for a product. **7**

OR

Q-3 **Attempt all questions**

(a) Discuss personnel facilities required in pharmaceutical industry. **7**
(b) Write SOP for operation of Disintegration test machine. **7**

SECTION – II

Q-4		**Define the following terms:**	**(07)**
	a.	Retrospective validation	**1**
	b.	Schedule M	**1**
	c.	Sterilization	**1**
	d.	Cleaning validation	**1**
	e.	Qualification	**1**
	f.	Calibration	**1**
	g.	Prospective process validation	**1**
Q-5		**Attempt all questions**	**(14)**
	(a)	Describe validation protocol for cleaning process.	**7**
	(b)	Describe various parameters to be validated for sterilization of parenteral dosage forms.	**7**
		OR	
Q-5		**Attempt all questions**	**(14)**
	(a)	Draw a neat sketch of RMG. Enlist the Installation qualifications (IQ) and Operation qualifications (OQ) for RMG.	**7**
	(b)	Explain validation protocol and its contents.	**7**
Q-6		**Attempt all questions**	**(14)**
	(a)	Discuss the equipments required in manufacturing of oral solid dosage forms as per schedule- M.	**7**
	(b)	Write a note on validation of dry heat sterilizer.	**7**
		OR	
Q-6		**Attempt all Questions**	**(14)**
	(a)	Write a note on validation of fluid bed dryer.	**7**
	(b)	Write the requirements of plant and equipments for the manufacture of ophthalmic preparations under revised schedule M.	**7**