Code No: B134204 **R13** SET - 1

IV B. Pharmacy II Semester Supplementary Examinations, July/August - 2017
QUALITY ASSURANCE, GMP & GLP

Time: 3 hours Max. Marks: 70

Note: 1. Question Paper consists of two parts (**Part-A** and **Part-B**)
2. Answering the question in **Part-A** is Compulsory
3. Answer any **THREE** Questions from **Part-B**

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PART –A

1.	a)	Differentiate quality control and quality assurance	(4M)
	b)	Write short notes on responsibilities of plant manager.	(3M)
	c)	Write the guidelines followed for maintenance of stores	(3M)
	d)	Write in brief on significance of SOP for labelling	(4M)
	e)	What is batch release document?	(4M)
	f)	Write in brief on processing of a complaint	(4M)

PART -B

2.	a)	Explain the significance of cGMP in industry	(10M)
	b)	Write in brief on measures to be taken for environment control in pharmaceutical industry	(6M)
3.	a)	Write in detail on the GMP issues pertaining to non-technical personnel	(6M)
	b)	Write in detail on change control protocols for R&D division of a pharmaceutical industry	(10M)
4.		Write short notes on	
		a) Guidelines to be followed for purchase of equipment	(8M)
		b) Safety time and reorder time	(8M)
5.		Elaborate on	
		a) In-process quality controls for injectibles	(6M)
		b) Quality audit	(10M)
6.	a)	Write in detail on GLP protocols for data handling	(8M)
	b)	Explain the guidelines to be followed for quality review process of analytical instruments	(8M)
7.		Write short notes on	
		a) Qualification of equipment	(6M)
		b) Handling of rejected and recovered products	(10M)
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