

Name : .....

Student Admn. No : .....

**School of Medical and Allied Sciences**  
**Continuous Assessment Test (CAT) - 2018 Semester: Winter, 2017-18**  
[Programme : B.Pharm ] [Semester: 8 ]

**Course Code:** PCY409  
**Course Title :** Quality Assurance and Validation  
**Time :** 1.30 Hrs  
**Max Marks :** 50

**Instructions :** 1. Attempt any one from 15 Marks Questions  
2. Attempt any two from 10 Marks Questions

S.No	Course Outcome	Knowledge Level	Question	Marks
1	CO 1	KL 3	Analyze ISO 9000 series.	5
2	CO 1	KL 3	Illustrate GLP.	5
3	CO 1	KL 3	Analyze between cGMP & GMP ?	15
			Analyze following-	
4	CO 1	KL 3	a) GLP b) USFDA c) WHO guidelines?	15
5	CO 2	KL 3	Analyze the importance of maintenance of records in pharmaceutical industry?	5
6	CO 2	KL 6	Analyze content and format of NDA filing ?	10
7	CO 2	KL 3	Analyze the content and role of SOP in pharmaceutical industry ?	10
8	CO 2	KL 3	Illustrate the list of documents required for new drug approval ?	10