	SanjayGhodawatUniversity,Kolhapur EstablishedasStatePrivateUniversityunder Govt.ofMaharashtra.ActNo XL,2017	2019-20 EXM/P/09/00
Year and Program **Final.Y.B.Pharm**	**School of Pharmaceutical Sciences**	**Department:Pharmacy**
Course Code:BP702T	**CourseTitle : Industrial Pharmacy II**	**Semester – VII**
Date: 27 Dec 2022 **Day: Tuesday** **Time: 10:30 to 1:30**	**Examination:End Semester**	**Max Marks:75**

Instructions: 1)All questions arecompulsory.
2) Draw a neat labeled diagram if necessary.

		Marks	**Bloom's Level**	**CO**
Q.1	**Objective Type Questions (10X2)**	**20**		
a)	Explain the 5 Methods used in pilot plant scale up technique.	02	1	1
b)	Define Quality.	02	1	4
c)	Describe in short Quality assurance.	02	2	4
d)	Explain in short Quality control.	02	2	4
e)	State the function of CDSCO.	02	1	5
f)	State the vision and mission of NABL.	02	1	5
g)	Explain the history of regulatory affairs.	02	2	3
h)	Define Bioequivalence.	02	1	3
i)	States in short ISO 14000 series.	02	1	4
j)	Define New Drug Application (NDA).	02	1	3
Q.2	**Long Answers (Answer 2 out of 3)**	**20**		
a)	Describe National Accreditation Board for testing and Calibration Laboratories (NABL).	10	2	5
b)	Discuss the parts of Investigator Brocher's (IB).	10	2	3
c)	Describe in detail SUPAC guideline for component and composition.	10	2	1

		35	**Bloom's Level**	**CO**
Q3	**Short Answers(Answer 7out of 9)**			
a)	Discuss the SUPAC guideline for manufacturing site changes.	05	2	1
b)	Explain in detail GLP.	05	2	4
c)	Describe in detail Pilot plant design for semisolid	05	2	1
d)	Discuss the state licensing authority.	05	2	5
e)	Explain the biostatics in detail.	05	2	3
f)	Outline the concept of out of specification (OOS).	05	3	4
g)	Explain technology transfer regulatory agency in India	05	2	2
h)	Describe certificate of Pharmaceutical Product.	05	2	5
i)	Explain the Non-clinical drug development in detail.	05	2	3

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