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BL-3105 Seat No._____

M. Pharm. (Sem. II) Examination

March / April - 2014

PY20201 : Global Regulatory Requirements

Time : **3** Hours] [Total Marks : **70**

Instructions : **1.** Attempt any five questions out of seven.

2. Make suitable assumptions wherever necessary with figure and table.

3. Figure to right indicate marks.

1.	A	Give Principle and Concept of global regulatory policy for Pharmaceuticals.	**7**
	B	Briefly discuss the Validation of Equipments in Pharmaceuticals.	**7**
2.	A	Briefly discuss the analytical method development for dosage forms.	**7**
	B	Write a note on ERP Systems.	**7**

3.	A	Discuss Concept and Applications of ORANGE Book.	7
	B	Briefly discuss the various phases of Drug Development.	7
4.	A	Discuss Content and Applications of NDA.	7
	B	Discuss Format and Applications of IND.	7
5.	A	Discuss Applications and basic procedural steps of DMF.	7
	B	Write a note on Freedom of information.	7
6.	A	Briefly discuss the concept of Para I to IV in regulatory Systems.	7
	B	Briefly discuss about WHO Guidelines in Pharmaceutical products.	7
7.	A	Write a note on ANVISA.	7
	B	Write a note on SUPAC.	7