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BL-3103 Seat No._____

M. Pharm. (Sem. II) Examination

March / April - 2014

(PY20201) Regulatory Affairs & New Drug Application

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 the right indicates full marks.

1	a	Discuss education regulation of The Pharmacy Act 1948.	**7**
	b	Give constitution of Pharmacy Council of India.	**7**
2	a	Write on US-FDA guidelines for clinical trials for drugs and dosage forms.	**7**
	b	Write note on clinical trial protocol design.	**7**

3	a	Discuss various regulatory aspects for pharmaceutical & bulk drug manufacturing.	**7**
	b	Give aim, objectives and salient features of prevention of Consumer Protection Act.	**7**
4	a	Enumerate various certification and standardization agencies around the world and explain any one in detail.	**7**
	b	Write a note on Drug Master File.	**7**
5	a	Explain objectives, submission procedure, format and contents of NDA.	**7**
	b	Write a note on Material Safety Data Sheet.	**7**
6	a	Discuss guidlines related to Import of Pharmaceutical Products as per D and C Act.	**7**
	b	Write a note on Central Drug Laboratory.	**7**
7	a	Discuss quality, safety and legislation for herbal/cosmetic products.	**7**
	b	Briefly describe contents of Pharmaceutical dossier as per the e-CTD format.	**7**