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Roll Tota	al No	o. of Questions: 06 M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1) REGULATORY AFFAIRS	s : 01
		Subject Code: MPH-104T M.Code: 74660	
Tim	Time: 3 Hrs. Max. Mark		
INST 1. 2.	Atte	TIONS TO CANDIDATES: empt any FIVE questions out of SIX questions. th question carries FIFTEEN marks.	
1.	Di	scuss the following with suitable examples and/or flow charts:	
	a.	ECTD	5
	b.	Scale-up process approval	5
	c.	Regulation for combination products	5
2.	a.	Discuss the NDA regulatory approval process with suitable example.	8
	b.	Write a note on outsourcing BA-BE studies to CRO.	7
3.	\mathbf{W}_{1}	rite short notes on the following:	
	a.	Drug product performance	5
	b.	Master formula record	5
	c.	Post marketing surveillance	5
4.		Give a detailed account on development of clinical trial protocol for an anti-depressan drug.	
5.	\mathbf{W}_{1}	rite short notes on the following:	
	a.	ICH-S guidelines	8
	b.	Regulatory requirements of MHRA	7
6.	Di	scuss the following with suitable examples:	

NOTE: Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

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a. IND

c. HIPAA

b. Dossier (IMPD)