M. Pharm. First Semester (Pharmaceutics) (New)

35320 : MPH 104 T - Regulatory Affairs

P. Pages : 1 | AU - 0751

Time : Three Hours | Max. Marks : 75

Notes : 1. All question carry equal marks.
2. Answer **any five** question.
3. Use of pen Blue/Black ink/refill only for writing the answer book.

1.		Explain in detail about B.A, B.E study & write the role of CRO in B.A B.E study.	15
2.	i)	Explain the impact of Hatch - Waxman Act on drug development process.	8
	ii)	Comment on post marketing surveillance.	7
3.		Explain in detail new drug application & add a note on INDA.	15
4.	i)	Discuss in detail about "investigator" in relation to clinical trials.	10
	ii)	Comment on HIPAA.	5
5.	i)	Explain in detail ICH Q1B in relation to photostability of new drug substance.	8
	ii)	Discuss about stability testing of API & finished pharmaceutical product as per WHO.	7
6.	i)	Discuss in detail about CTD & ECTD..	8
	ii)	Discuss about regulation of medical devices.	7
7.		Write notes on **any two.**	15
		i) Pharmacovigilance.	
		ii) CMC for new drug.	
		iii) Regulation of prescription drug as per TGA.	
		iv) SUPAC.	

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