Code No: IP32D/R13

M. Pharmacy II Semester Regular/ Supplementary Examinations, July-2016

DRUG REGULATORY AFFAIRS

(Common to All Branches)

Time: 3 Hours **Max. Marks: 60**

Answer any FIVE Questions
All Questions Carry Equal Marks

1.	a	What are the reasons for conducting pre-formulation studies?	4
	b	Explain pre-formulation studies for semi-solid dosage forms.	8
2.	a	Bring out the salient differences between Indian and US laws regulating to Patent approval process	8
	b	Define Intellectual Property Rights and explain different types.	4
3.	a	Define clinical trial. Explain different phases of clinical trials.	6
	b	Explain statistical analysis of clinical data.	6
4.	a	Explain stability testing of drug substances as per Indian regulatory requirements.	6
	b	Explain analytical method validation parameters in detail.	6
5.	a	Discuss the biopharmaceutical considerations from the point of view of formulation and manufacturing process.	8
	b	Write note on pharmacokinetic validation.	4
6.	a	What are regulatory guidelines for packing materials?	6
	b	Explain how evaluation of closures will be done as per Indian regulatory authorities.	6
7.	a	What are regulatory requirements as per Indian regulatory authorities for manufacturing process of active ingredients	6
	b	Discuss current guidelines and developments as per regulatory requirements of European community for clinical bioavailability	6
8.	a	Discuss regulatory guidelines as per US on clinical study design and documentation.	8
	b	Explain the essential drug regulatory guidelines in the pre-formulation studies of Occular preparations.	4

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