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Rol	II No. Total No. of Pa	ges : 01
Total No. of Questions: 06 M.Pharmacy (Pharmaceutical Analysis) (2017 & Onwards) (Sem1) PHARMACEUTICAL VALIDATION Subject Code: MPA-103T		
Paper ID: [74695] Time: 3 Hrs. Max. Marks		
INS [*] 1. 2.	TRUCTIONS TO CANDIDATES: Attempt any FIVE questions out of SIX questions. Each question carries FIFTEEN marks.	
Q1	a) Define Validation. How re-validation of validation process differs from p validation and concurrent validation?	rospective (7)
	b) Highlight the validation steps for the calibration of manufacturing equipment.	(8)
Q2	Enumerate the qualification of:	
	a) Pipette and Measuring cylinder	(7)
	b) UV-visible spectrophotometer	(8)
Q3	a) What are the necessary qualifications of water system?	(7)
	b) Highlight the validation of cleaning of filling area.	(8)
Q4	a) Give ICH guidelines for the validation of analytical method.	(7)
	b) Enumerate computer system validation.	(8)
Q5	a) Enumerate the rights and responsibilities of patentee.	(5)
	b) Distinguish between IP, IPP, IPR	(5)
	c) Explain penalties for the violation of intellectual property.	(5)
Q6	Write note on:	
	a) FAT	(5)
	b) Cleaning of equipment	(5)
	c) Significance of TOT	(5)
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