M. Pharm. Second Semester (Quality Assurance) (New)

35359 : Audits and Regulatory Compliance : MQA 203 T

P. Pages : 1 | AU - 0778

Time : Three Hours | Max. Marks : 75

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Notes : 1. All question carry equal marks.
2. Answer **any five** question.
3. Illustrate your answer necessary with the help of neat sketches.

1.		Write in detail about planning for conduct of audit in pharmaceutical manufacturing plant.	15
2.		Write in detail steps involved in audit of tableting process.	15
3.	a)	Write a note on Resources for conducting audit.	8
	b)	Write in short Evaluation parameters involved in audit of any one pharmaceutical product.	7
4.		Write the auditing methodology adopted for microbiological auditing of packaging materials.	15
5.		Write importance of auditing. HVAC system for quality assurance of manufactured products.	15
6.		Write in detail cGMP Regulations for quality goods manufacturing.	15
7.		Write in detail about objectives and management of audit.	15

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