



**SHREE H.N.SHUKLA INSTITUTE OF PHARMACEUTICAL
EDUCATION AND RESEARCH, RAJKOT**



B.PHARM SEMESTER-VII, INTERNAL EXAM (2021-22)

Subject code: BP706TT		Date: 14/10/2022
Sub: QUALITY ASSURANCE		Total Marks: 20
Time: 10:30AM TO 11:30AM		Enroll. No:
Write in detail: (ATTEMPT ANY FOUR)		
Q.1	Describe general protocol for conduct of non-clinical laboratory study.	(5)
Q.2	Enlist the parameter to be checked for method validation. Explain any two.	(5)
Q.3	Describe the procedure of NABL accreditation in India.	(5)
Q.4	Explain the plant layout for sterile facility in pharmaceutical industry.	(5)
Q.5	Give a brief note on ISO 9000 and ISO 14000? Discuss various steps for its registration.	(5)