MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

MPharm – Pharmaceutical Analysis Specialization

MPharm Semester I – End Semester Makeup Examination, January 2023

PCH-MPA103T. Pharmaceutical Validation

Date: 20-01-2023 **Duration: 3 hr.** **Max. Marks: 75**

Instructions: Answer ALL questions.

Answer the following	**5 Q × 10 marks = 50 marks**
Section A	
1. What is calibration? Explain the calibration of volumetric apparatus with suitable example 10M	
2a. What is LOD and LOQ of an analytical method? Explain how LOD and LOQ is established during analytical method validation 5 M 2b. What is specificity of an analytical method? How specificity studies are carried out for a chromatographic method including peak purity analysis 5 M	
3a. Discuss in detail stages involved in grant of a patent in India with the help of a flow chart 5M 3b. What are non-patentable inventions under section 3 of Indian Patent Act 1970? 5M	
4. Explain the operation qualification of UV visible spectrophotometer and High-Performance Liquid Chromatography. 10M	
5. Explain Installation qualification and Design qualification in detail. Explain the contents of Validation master plan 10M	
Answer the following	**5 Q × 5 marks = 25 marks**
Section B	
6. What is cleaning validation? Explain types of sampling techniques in cleaning validation 5M	
7. Explain potential items for a cleaning validation masterplan 5M	
8. write a note on CFR part 11 and GAMP 5 M	
9. How filter leak test and air flow velocity check of an HVAC system are performed? Explain 5M	
10. Explain in detail Prospective validation and revalidation 5M	