BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS:M.Pharm **SEMESTER : II**
BRANCH:
Pharmacy **SESSION : SP/22**

SUBJECT: MQA202T Pharmaceutical Validation

TIME: **FULL MARKS: 75**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 15 marks and total 105 marks.
2. Candidates may attempt any 5 questions maximum of 75 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a) Why revalidation is required in pharmaceutical industry? Discuss in detail about different types of validation [7]

Q.1(b) Define & differentiate between calibration and validation. Write in detail on organization for validation [8]

Q.2(a) Why qualification is necessary incase instruments? Give a detail note on various types of qualification with suitable examples. [7]

Q.2(b) What do you mean by FAT & SAT? Explain in detail about various aspects of FAT & SAT. [8]

Q.3(a) What is requalification? Discuss the qualification of dry heat sterilization process. [7]

Q.3(b) Explain the calibration of HPLC & GC [8]

Q.4(a) Why validation of water system required? Explain about validation of pharmaceutical water system & pure stream [7]

Q.4(b) Write the qualification of friability test apparatus and tablet hardness tester. [8]

Q.5(a) Define Process Validation and write about types of process validation. Enlist documentation of process validation [7]

Q.5(b) Explain through a case study of process validation of any solid oral dose formulation that what are critical components, steps and documents involved in it? [8]

Q.6(a) Explain in detail what are steps for cleaning method development for any equipment? [7]

Q.6(b) Write short note on (any two only): [8]

i. Computerized validation requirements for 21 CFR part 11
ii. Computerized validation requirements for GAMP
iii. CIP
iv. PCT

Q.7(a) What are mechanisms of protection of I.P? Discuss in detail on type of patents and filing of patent. [7]

Q.7(b) What is patent infringement and explain significance of transfer of technology (TOT)? [8]

::::: 29/04/2022:::::