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

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

SUBJECT: MQA203T AUDITS AND REGULATORY COMPLIANCE

TIME: 3.00 Hours **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) What do you mean by compliance classification in auditing? Write the SOP & significance of auditing in pharmaceutical industry. [7]

Q.1(b) What is the purpose of FDA audit? Explain the auditing procedure with suitable flow chart. [8]

Q.2(a) What are reasons for FDA's CGMP guidance? Discuss the significance of manufacturing in quality system. [7]

Q.2(b) Why quality audit is necessary? Write about auditors' tools, audit observations, audit report & IQARP. [8]

Q.3(a) Describe how vendor audit is related to QbD involving understanding of product variability? [7]

Q.3(b) Write short note on: [8]
i. PCNC
ii. PCC
iii. Gang printing

Q.4(a) Discuss steps for preapproval auditing of tablet manufacturing process? [7]

Q.4(b) Describe stock culture? Write about storage and disposal of storage culture? [8]

Q.5(a) Describe key parameters in auditing a microbiological and sterility testing quality [7]

Q.5(b) Write short note on : [8]
i. Antimicrobial Effectiveness Test
ii. Identity Testing of Microorganisms
iii. Biosafety levels

Q.6(a) Justify the role of physical & chemical process in ETP. [7]

Q.6(b) Write notes on analysis of energy consumption and building function with respect to HVAC. [8]

Q.7(a) Explain about CGMP and the different concepts of modern quality systems [7]

Q.7(b) Discuss about 21 CFR CGMP regulations related to management responsibilities [8]

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