

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

CLASS: M. PHARM.
BRANCH: PHARMACY

SEMESTER : II
SESSION : SP/19

SUBJECT: MQA204T PHARMACEUTICAL MANUFACTURING TECHNOLOGY
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.
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- Q.1(a) What do you mean by Pharmaceutical Packaging? Discuss different types of packing materials. [7]
Q.1(b) Describe Procedure to get drug License for setting up of Drug manufacturing Industry. [8]
- Q.2(a) Discuss the validation of dry heat sterilization method in detail. [7]
Q.2(b) Discuss biological indicators used for method validation by various sterilization methods. [8]
- Q.3(a) Discuss requirement of cGMP in drug formulation industry. [7]
Q.3(b) How will you check the sterility of any Pharmaceutical products? Discuss various aspects in detail. [8]
- Q.4(a) Discuss Production, planning and Control in Drug manufacturing Industry. [7]
Q.4(b) What do you mean by in-process Control in drug manufacturing? Write for Tablet and Oral Liquid. [8]
- Q.5(a) Which sterilization method is effective in destroying endotoxin / pyrogen? [7]
Q.5(b) Draw flow chart of Capsule, injectables and ointment manufacturing. [8]
- Q.6(a) Discuss how control strategy is adopted in QbD with example. [7]
Q.6(b) Explain in detail the input attributes, process parameters and quality attributes of unit operations with examples. [8]
- Q.7(a) Define the terms QTPP and CQA. Write short notes on quality risk management systems with an example of its application. [7]
Q.7(b) What are the factors considered in defining QTPP and CQA and write in detail different QTPP elements and CQA's with proper justification with an example? [8]

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