

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

CLASS: M.PHARM  
BRANCH: PHARMACY

SEMESTER : I  
SESSION : MO/19

SUBJECT: MQA103T QUALITY CONTROL AND QUALITY ASSURANCE

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) Define Quality. Justify the role of quality assurance in pharmaceutical industry [7]  
Q.1(b) What do you mean by QSEM in ICH? Explain in detail about CPCSEA guideline. [8]
- Q.2(a) Discuss Title 21 Part 211 Subpart C [7]  
Q.2(b) Justify the importance of Organization and Personnel Title 21 Part 211. [8]
- Q.3(a) What is IPQC? Justify the role of IPQC in quality management. [7]  
Q.3(b) Explain the IPQC parameters for various dosage forms and highlight the trouble shooting parameters for capsules. [8]
- Q.4(a) Discuss the different types of SOPs available for QC Lab in details. [7]  
Q.4(b) Justify the six steps to developing a SOP. [8]
- Q.5(a) Explain about the process deviations and change control [7]  
Q.5(b) What is IPR? Explain the concept of trademark, copyright and patents with suitable examples [8]
- Q.6(a) Discuss the specific tests / criteria for Oral Liquids as per ICH Q6. [7]  
Q.6(b) Discuss the details of reporting degradation products content of batches as per ICH Q3. [8]
- Q.7(a) Discuss the importance of sanitation of manufacturing premises. [7]  
Q.7(b) Discuss in detail the role of GMP in quality control of pharmaceutical products. [8]

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