

9/11/24

Seat Number

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DADU-72

MQA 104T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(161104)

Total Page : 1]

Time: 3 Hours

Max. Marks : 75

**Instruction to Candidates:**

1. Do not write anything on question paper except Seat No.
  2. All questions are compulsory.
  3. Figures to right indicate full marks.
  4. Students should note, no supplement will be provided.
  5. Graph or diagram should be drawn with the black ink pen or black HB pencil.
  6. Solve any **Five questions** from the following.
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1. Describe large scale manufacturing techniques including formula, equipment, process, stability and quality control for solid dosage forms in detail. 15
  2. Write about significance and design of Pilot plant scale up. How does it differ from large scale manufacturing. Discuss the challenges in scale up of new drug products. 15
  3. Discuss various issues faced in modern drug packaging. Give the quality control tests for glass as a packaging material. Enlist types of Pharmaceutical Packaging. 15
  4. What is technology transfer? Discuss various documents involved in technology transfer of a dosage form. 15
  5. Discuss in detail stability testing during product development as per ICH guidelines. 15
  6. What are SUPAC and BACPAC? Discuss in detail SUPAC guidelines for changes in formulation, site, equipment and process along with suitable examples. 15
  7. How is technology transferred from R & D to production? Give detailed overview of various quantitative models in technology transfer. 15
  8. What is product registration? Discuss registration of bulk drugs and finished formulations in India as per CDSCO 15