

Seat Number

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**DADU-22**

**MQA 202T : PHARMACEUTICAL VALIDATION**

**(161202)**

**Total Page : 1]**

**Time: 3 Hours**

**Max. Marks : 75**

**Instruction to candidates:**

- 1 Do not write anything on question paper except Seat number.
  - 2 Graph or diagram should be drawn with black ink pen being used for writing paper or black HB pencil.
  - 3 Students should note, no supplement will be provided.
  - 4 Solve any Five of the following questions.
  - 5 Figures to the right indicate full marks.
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1. Define: Qualification. How to perform OQ and PQ of disintegration test apparatus? 15
  2. Explain in detail validation parameters of water system. 15
  3. Explain in brief a life cycle approach of process validation. 15
  4. Write in detail Analytical method validation as per ICH Q2R1. 15
  5. a) Explain in brief validation master plan. 08  
b) Enlist validation parameter of HVAC system and explain in brief any two parameters. 07
  6. Write a note on the qualification of:  
a) Cleaning in place (CIP). 08  
b) 21 CFR Part 11 and 820. 07
  7. Write in brief about:  
a) Copyright and Trademark 08  
b) Types of patent application. 07
  8. Write in brief about:  
a) Write in detail equipment qualification of tablet compression (machine). 08  
b) PQ of Friability test apparatus. 07