

C.U.SHAH UNIVERSITY**Summer Examination-2018****Subject Name:** Pharmaceutical Validation**Subject Code:** MQA202T**Branch:** M. Pharm (QA)**Semester:** 2**Date:** 25/04/2018**Time:** 10:30 To 01:30**Marks:** 75**Instructions:**

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
 - (2) Instructions written on main answer book are strictly to be obeyed.
 - (3) Draw neat diagrams and figures (if necessary) at right places.
 - (4) Assume suitable data if needed.
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Q-I Attempt all the following questions. [2X10]=20

- a) Describe in brief Calibration. [2]
- b) Explain the term Process Validation. [2]
- c) Describe briefly Retrospective Validation. [2]
- d) Explain the term Operational Qualification. [2]
- e) Describe in brief Performance Qualification. [2]
- f) Write the objectives of Cleaning Validation. [2]
- g) Describe in brief Trademark. [2]
- h) Explain the term Documentation. [2]
- i) Explain briefly Claim. [2]
- j) Describe briefly Statistical Process control. [2]

Q-II Attempt any two: [2X10]=20

- a) Describe in detail the equipment qualification of FBD. [10]
- b) Discuss in detail the performance qualification of autoclave. [10]
- c) Explain the validation and qualification of HVAC system. [10]

Q-III Attempt any seven: [7X5]=35

- a) Write the various phases in process validation. [5]
- b) Explain the validation life cycle with the help of flow chart. [5]
- c) Write a note validation master plan. [5]
- d) Describe bracketing approach during cleaning validation. [5]
- e) Explain the various steps for validation and acceptance criteria in wet granulation process for coated tablets. [5]
- f) Describe the various types of inventions which are non-patentable in India? [5]
- g) Write the general rules for PCT. [5]
- h) Write a short note on patent licensing. [5]
- i) Describe the benefits of IPRs to improve the quality of research work. [5]

