HDU-02011244 Seat No. _____

M. Pharm. (Sem. III) (CBCS) (External) Examination

November / December – 2017

Quality Assurance : Core - VII

(Validation, Product Development & Stability Testing (Theory))

Time : **3** Hours] [Total Marks : **80**

Instructions : (1) Answer and tie up both the sections separately.
(2) Figures to the right indicates marks.
(3) Answer the three (03) questions from each section.
(4) Question one (01) and question five (05) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION - I

1 Explain the following terms with suitable example : **14**
(Any **seven**)

(a) Dead Spot (in sterilizer)

(b) Verification

(c) Technology transfer

(d) Concurrent Validation

(e) ICH Q2 R1

(f) Order of reaction

(g) Biological indicators

(h) Photostability

(i) Revalidation

(j) Change control

2 Answer the following :

(a) Write a definition, scope and principle of Validation Master Plan. Enlist the factors which are considered in validation master plan and describe. **7**

(b) Write a short note on validation of Dry powder mixer and FBD. **6**

3 Answer the following :

(a) Explain various aspects of computer system validation. **7**

(b) What is the objective of accelerated stability study? Discuss the limitation of it. **6**

4 Answer the following :

(a) Write a brief informative note on validation of Gaseous sterilization **7**

(b) Write a short note on Process Validation. **6**

SECTION - II

5 Write a short note **two** out of three : **14**

(a) Cleaning validation

(b) Prospective validation

(c) Validation of Pharmaceutical water.

6 Answer the following :

(a) Write a brief note on analytical method validation as per ICH. Discuss the parameters of it. **7**

(b) What is ICH guidline? Give information about the structure of ICH guideline. Write informative note on role of Steering committee. **6**

7 Answer the following :

(a) Write a short note on validation of air handling equipment and facilities in sterile and non-sterile areas. **7**

(b) Draw the "V" Model for process validation. Draw and Discuss "Cause and Effect" model for prospective validation. **6**

8 Answer the following :

(a) Define Process Validation. Discuss Process Validation of Finished products. **7**

(b) Enumerate different HVAC system parameters used in qualification of pharmaceutical facility **6**