HDU-02012112 Seat No. _____

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

November / December - 2017

Pharmaceutical Validation
(Drug Regulatory Affairs)

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 (1) and question Five (05) are compulsory.
(5) Draw neat and clea.n diagrams as required.

SECTION - I

1 Answer any seven out of 10 : **14**

(a) What is Performance qualification ?
(b) Define process validation.
(c) What is Operation qualification ?
(d) Define Accuracy. How it can be checked for analytical method ?
(e) Discuss ruggedness of an analytical method.
(f) Define LOD and LOQ.
(g) Define analytical method validation.
(h) Explain Prospective validation.
(i) Explain retrospective validation.
(j) When revalidation is required?

2 Answer the following questions: **13**

(a) Discuss use of statistical process control in validation. **7**
(b) Write a detailed note on cleaning validation. **6**

3 Answer the following questions: **13**

(a) Describe DQ, IQ, OQ and PQ steps involved in validation of autoclave. **7**
(b) How validation of water for injection is carried out ? **6**

4 Answer the following questions : **13**

(a) How validation of dry heat sterilizer is carried out ? **7**

(b) Discuss about validation of facilities. **6**

SECTION - II

5 Answer any two out of three (07 x 02) **14**

(a) Discuss validation of heating ventilation and air conditioning.

(b) Discuss validation of drying process.

(c) Discuss validation of granulation process.

6 Answer the following question : **13**

Write a detail note on: validation of sterile and non-sterile facility.

7 Answer the following questions: **13**

(a) Discuss about medical device and packaging validation issues **7**

(b) Write a detailed note on SUPAC. **6**

8 Answer the following questions: **13**

(a) Discuss WHO guidelines for calibration of equipments. **7**

(b) How process validation of finished products can be carried out ? **6**