Registration no: | | | | | | | | | | |

Total Number of Pages: 02 **B.PHARM**
PH 8.4

8th Semester Regular / Back Examination – 2017-18
Quality Assurance and GMP
Branch: B.Pharma
Time: 3 Hours
Max marks: 70
Q Code:C239

Answer Question No.1 which is compulsory and any five from the rest.
The figures in the right hand margin indicate marks.
Answer all parts of a question at a place.

Q1 **Answer the following questions : *Short answer type :*** **(2 x 10)**

a) Define audit and classify it.
b) What is schedule M? What are its elements and sub elements?
c) Define quality policy?
d) What do you mean by process validation and process optimization?
e) What is equipment validation and what are its steps?
f) Classify and signify the role of HVAC systems in environment control.
g) What do you mean by master formula record? What should an ideal MFR contain?
h) What do you mean by Mean Kinetic temperature? How does temperature influence stability of pharmaceutical products?
i) Signify the role of DRA in regulating pharmaceutical product quality.
j) Expand the terms ISO and ICH.

Q2 **Write short notes on:**

a) What is cleaning validation and Rinse samples? **(5)**
b) Swab technique. **(5)**

Q3 **a)** Write about ideal requirements of warehouse for pharmaceutical products both RM and FP. **(5)**
b) Terminal sterilisation and sterile filtered products **(5)**

Q4 **a)** Retrospective validation. **(5)**
b) Analytical validation. **(5)**

Q5 **a)** Discuss briefly about functions of drug regulatory authority as per U.S. **(5)**
b) Discuss briefly about DRA functionality as per Indian scenario. **(5)**

Q6 **a)** Briefly write about product recall. **(5)**

b) Complaints handling is a vital process in any pharmaceutical industry. Justify. **(5)**

Q7 Write a note on TQM along with its principles and rules. **(10)**

Q8 **Write short notes on Any Two:** **(5 X 2)**

a) SOP
b) ISO
c) Good Manufacturing Practices
d) Role of Quality Assurance in Pharmaceutical Industry.