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

Total Number of Pages: 02

MPHARM
M.PH2C.1

2nd Sem M. Pharm. Regular Examination – 2016
QUALITY ASSUANCE OF PHAMACEUTICALS
Time: 3 Hours
Max marks: 70
Q.CODE:W992
Answer Question No.1 which is compulsory and any five from the rest.
The figures in the right hand margin indicate marks.

Q1 Answer the following questions: (2 x 10)

a) What do you mean by batch release documents?

b) What do you mean by retraining? Mention its significance.

c) What is calibration interval? Give examples.

d) Give example of two human blood products.

e) Define KAIZEN principle and signify its role in QA.

f) How microbiological monitoring is conducted?

g) Differentiate critical defects and major defects.

h) Differentiate between efficacy and effectiveness.

i) Justify why retention of samples is necessary in a pharmaceutical industry?

j) What is customer satisfaction index?

Q2 Write short notes on. (5x2)

a) What is Quality Council? Mention its job.

b) SOP

Q3 Write short notes on. (5x2)

a) Guidelines for QA of LVPs

b) What parameters are generally considered while purchasing equipments?

Q4 Write short notes on. (5x2)

a) Responsibilities of Production head and QC head

b) Evaluation of complaints received and recall procedure there off

Q5 a) Steps for vendor selection (5)

b) Write a note on good warehousing practice. (5)

Q6 What is the significance of SMF? Describe it in detail. (10)

Q7 Give a detail note on BMR. (10)

Q8 a) How is the tablet section audited? (5 x 2)
b) IPQC test for sterile products