Graphic Era HILL UNIVERSITY
Established by an Act of the State Legislature of Uttarakhand (Adhiniyam Sankhya 12 of 2011)
University under section 2(f) of UGC Act, 1956

Sessional II (Even) Semester Examination, May 2025

Roll no.....

Name of the Course and semester: B.Pharm VI Sem
Name of the Paper: Pharmaceutical Quality Assurance
Paper Code: BP606T
Time: 1.5-hour

Maximum Marks: 30

Note:
(i) This question paper contains three sections.
(ii) All the questions are compulsory.

Section-A

Q1. Multiple Choice Questions – Attempt all questions **(10 X 1 = 10 Marks)**

a. Surface treatment test is also known as : (CO3)
i. Chemical resistant test
ii. Glass grain test
iii. Etching test
iv. Inner surface test

b. Non volatile residue test is done according to : (CO3)
i. Welfare 2007, USP38 and NF33
ii. Welfare 2008, USP38 and NF33
iii. Welfare 2007, USP38 and NF34
iv. Welfare 2007, USP39 and NF33

c. Water attack test is mainly done for : (CO3)
i. Glass I type
ii. Glass II type
iii. Glass III type
iv. Glass IV type

d. Organisational study plans and SOPs are stored in : (CO3)
i. Records storage facility
ii. Storage and retention of records
iii. Apparatus and materials facility
iv. Archieve facility

e.Quality Assurance unit is the unit work under (CO3)
i. GLP
ii. GMP
iii. QA
iv. SOPs

f. CAPA stands for : (CO4)
i. Correction about particular action
ii. Corrective and preventive action
iii. Corrective and preserved action
iv. Correct and prevent action

g. Public alert recall is done for : (CO4)
i. Class I hazard
ii. Class II hazard
iii. Both (i) and (ii)
iv. Evaluation of recall

h. As per D &C Act and rules, handling & disposal should be done as per : (CO4)
i. Biomedical waste (Management & Handling) Rules, 1995
ii. Biomedical waste (Management & Handling) Rules, 1996
iii. Biomedical waste (Management & Handling) Rules, 1997.
iv. Biomedical waste (Management & Handling) Rules, 1998.

i. In Master Formulae Record, PRC stands for : (CO4)
i. Product referral code
ii. Product recall code
iii. Product reference code
iv. Product request code

j. Type 3 Drug Master File includes the details of : (CO4)
i. Operating procedure
ii. Drug substances
iii. FDA accepted information
iv. Packaging material

Section B

Q. 2 Short Questions: Attempt any two questions **(2X 5 = 10 Marks)**

a. Mention all types of facilities incorporated within a Pharmaceutical industry. (CO3)
b. Elaborate all the steps required during recall of any product from market after complaint (CO4)
c. Define DMF and enlist all the information provided within DMF. (CO4)

Section C

Q. 3 Long questions: Attempt any one question **(1X10 = 10 Marks)**

a. Elaborate different Quality control test for packaging materials (Glass). (CO3)
b. Define waste disposal management system . Explain different waste disposal methods for pharmaceutical products. (CO4)