

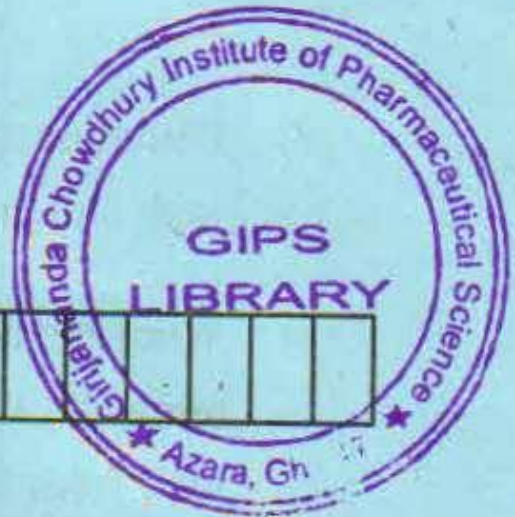
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PY 132804

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2017

B. Pharm. 8th Semester End-Term Examination

QUALITY ASSURANCE AND GMP

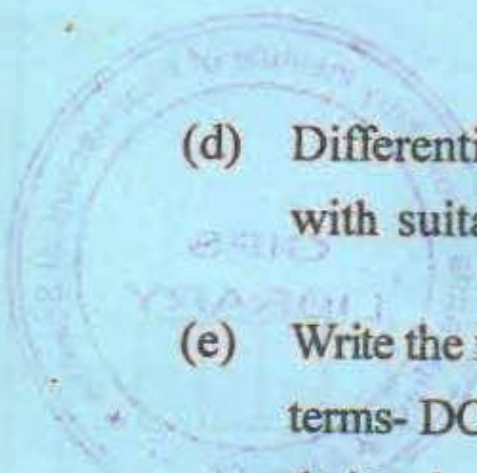
Full Marks – 100 Pass Marks – 35 Time – Three hours

The figures in the margin indicate full marks
for the questions.

Section-A

1. Answer any *ten* questions : 3×10=30
- (a) What is recovery factor ? How do you calculate recovery factor in cleaning validation ?
 - (b) What is the difference between robustness and ruggedness ?
 - (c) What is retrospective validation ? Illustrate with suitable example.

[Turn over

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- (d) Differentiate between records and documents with suitable examples.
- (e) Write the full form of the following abbreviated terms- DCGI, CDSCO, and USFDA. What are their roles in pharmaceutical regulation ?
- (f) What is the difference between calibration and validation ?
- (g) What are the different types of climatic zone for stability testing of drug products as per ICH guidelines ?
- (h) What are the four attributes of a quality pharmaceutical product ?
- (i) Define the following terms – quarantine area, line clearance, pass box.
- (j) What are MACO and NOEL ?
- (k) Name drugs covered under schedule C1, C&X.

Section – B

2. Answer any *eight* questions : 5×8=40

- (a) What is analytical method validation ? How do you evaluate the specificity of an analytical method as per ICH guideline ?
- (b) How the concept of Quality Assurance is different from Quality Control ?
- (c) Write a short note on Equipment qualification.
- (d) What is SOP ? Why SOPs are followed in pharmaceutical industry ?
- (e) List out the different elements of ISO 9000 quality standards and discuss briefly about any one of them.
- (f) "Quality should be built into the product". Justify the statement with respect to good manufacturing practices followed in pharmaceutical industry.
- (g) Write a short note on the principle of TQM.
- (h) What is IPR ? What are different types of protection provided under IPR ?
- (i) What are the post marketing regulations for drug development ?

Section-C

3. Answer any *three* questions : $10 \times 3 = 30$

- (a) What is validation ? Classify them. What is process validation ? How many types of process validation exist ? Describe briefly about any one of them. $2+1+2+1+4=10$
- (b) List out the various provisions of GMP as per Drugs and Cosmetics Act 1940 and discuss briefly about any five of them. 10
- (c) Discuss the stability testing protocols of drug products as per ICH guidelines with respect to selection of batches, testing frequency and storage conditions. 10
- (d) Discuss the salient features of D&C Act, 1940 to the manufacturing of drugs in India.