Total number of printed pages – 4

B. Pharm

PH. E1

Eighth Semester Examination – 2008

QUALITY ASSURANCE AND GMP

Full Marks – 70

Time : 3 Hours

*Answer Question No. **1** which is compulsory and any **five** from the rest.*

The figures in the right-hand margin indicate marks.

1. Answer the following questions in brief : 2 ×10

(i) What are the main guidelines of validation of depyrogenation ?

(ii) What is the main factors for validation of hard gelation capsules ?

(iii) What are the infomation shall be recorded for processing of a batch ?

(iv) Write the matter to be written in the label of a product containing schedule H drug as per drug rule.

(v) Write the SOP of batch numbering.

(vi) What are the precautions to be taken against mix-up and cross contamination in the manufacturing stage ?

(vii) How warehousing area shall be designed ?

(viii) How disposal of waste from pharmaceutical factory shall be done ?

(ix) Write the specifications of raw materials as per GMP.

(x) Write the main guidelines for analytical method validation.

2. Write in brief the salient features of Good Manufacturing Practices. 10

3. Write down the general guidelines on process validaton. 10

4. What are the factors to be considered for validation of Tablets and its packaging ? 10

5. Describe briefly the cleaning of non-sterile and cleaning and disinfection of sterile areas. 10

6. What do you mean by quality assurance ? Write briefly the salient features to ensure quality assurance. 10

7. Write the SOP guidelines for tablets and capsules. 10

8. Describe the procedure for product recalls and reprocessing and recovery of product residue. 10

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