MALIBA PHARMACY COLLEGE
M.Pharm. Semester 1
Internal Examination Nov-Dec. 2012
(040030103) Good Manufacturing and Good Laboratory Practices

Instructions:
1. Attempt all questions.
2. Write each section in a separate answer book.

SECTION 1

Q.1. Answer in brief: (Any 5) **(5)**

a. Differentiate between QA and QC.
b. What guideline is given for premises of penicillin manufacturing?
c. What is meant by 'in-process controls'?
d. Who are vendors?
e. What are utilities?
f. What are CIP and SIP equipments?

Q.2. Answer the following: (Any 5) **(10)**

a. What are the advantages of making SOPs?
b. What is vendor certification and decertification?
c. Write the significance of good documentation.
d. Enlist the factors considered while selecting premises for pharma plant.
e. Describe the procedure for recruiting new personnel.
f. Write the IPQC tests for tablet and capsule dosage forms.

Q.3. Answer in detail: (Any 4) **(20)**

a. Write a SOP for operation of a hot air oven.
b. Discuss the points to be remembered while writing a SOP.
c. Write the content of a master formula record.
d. Describe the GMP guidelines for selection and maintenance of equipments.
e. How should raw materials be received, stored and issued?

SECTION 2

Q.4. Define the following: (Any 5) **(5)**

a. Retention sample
b. Complaints
c. Recall
d. Salvaged goods
e. Reconciliation of labels
f. Warehouse

Q.5. Answer the following: (Any 5) **(10)**

a. What is line clearance?
b. Describe the layout of a warehouse.
c. Write the content of waste disposal records.
d. Explain the importance of WHO certification.
e. What are specifications? Write general content of finished product specifications.
f. Enumerate the tests performed on glass vials.

Q.6. Answer in detail: (Any 4) **(20)**

a. Explain the different types of WHO certifications.
b. Classify quality audits. Describe the qualities of a good auditor.
c. What is the scope of Sch L1? Discuss GLP guidelines with respect to 'facilities' of a testing laboratory.
d. Enlist the different documents maintained in a QC department and explain briefly the content of each.
e. Explain the responsibility of a study director as per GLP.

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