AT–1438

M.B.A. Semester—III Examination

(New Course)

PRODUCTION, MANAGEMENT IN PHARMACEUTICAL INDUSTRY

Paper—MBA/3503/PH

Time : Three Hours] [Maximum Marks : 70

Note :— (1) **ALL** questions are compulsory.

(2) Figure to the right indicate full marks.

SECTION—A

1. (a) Explain the significance of good manufacturing practices. Also discuss important processes in manufacturing Pharmaceutical Products. 14

OR

(b) What do you understand by the term Product recalls ? Explain in detail the procedure for product recall. 14

SECTION—B

2. (a) Define Validation. Explain the importance of validation. 7

(b) Suppose you are working as a warehouse in-charge in ABC Pharma Pvt. Ltd. What procedure will you follow in case of returned drug products and their disposition ? 7

OR

(c) Explain the importance of testing and release of finished products. 7

(d) You are working as a pharma consultant and a newly start pharma company wants to develop qualification protocol. As a Pharma consultant how will you assist Pharma company in this regards ? Justify. 7

3. (a) Explain how principles of layout plays a significant role in secondary pharmaceutical production. 7

(b) Suppose you are working as a Production Manager in Pharma Company. You want to make the Production unit fully automated but the management is not infavour of automated Production unit. As a production manager how will you convince management in this regards ? 7

OR

(c) Explain in detail the significance of Packaging Operations. 7

(d) You are working as a production manager in Neco Pharma Pvt. Ltd. How as a production manager will you take care of the operating environment within Neco Pharma Pvt. Ltd. ? Justify. 7

SECTION—C

4. (a) Discuss the role of Quality Control department for Pharma company. 7

(b) Explain in detail methods of Quality assurance. 7

OR

(c) Explain the role and significance of R and D department in Pharma company. 7

(d) Discuss the requirements and interpretation of ISO 9001 : 2000. 7

SECTION—D

5. Safety and health principles are universal, but how much action is needed will depend on the size of the organization, the hazards presented by its activities, the Physical characteristics of the organisation, Product or services, and the adequacy of its existing arrangements. Many of the features of effective safety and health management are analogous to the sound management practices advocated by proponents of quality management, environmental protection and business excellence. commercially successfully companies often excel at safety and health management as well precisely because they apply the same efficient business expertise to safety and health as to all other aspects of their operations. Organisations that manage safety and health successfully invariably have a positive safety culture and active safety consultation programmes in place. Successful organisations can establish and maintain a culture that supports safety and health. Pharmaceutical products being what they are, dealing with the health and healing of people, are subjected to rigid controls and stringent regulations. Safety is of paramount importance. A product even if it is a major earner for a company or a product group that is growing rapidly, if considered unsafe may have to be withdrawn. If the government decides that the product or category itself is not safe enough or is irrational, it may ban the use of the Product or Product category as the case may be. Pharmaceutical marketeers therefore should monitor closely the changing trends of products and the line of therapy not merely at the domestic level but on a global level. The Pharmaceutical companies in developed and advanced countries closely watch their products in terms of safety and efficacy.

(a) Analyse the case and identify the key issues involved in the case. 7

(b) Considering the above case why Safety Health and Environment (SHE) management system is important for Pharmaceutical industry ? Justify your answer with reasons. 7