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**PQ—21—2022**

**FACULTY OF PHARMACEUTICAL SCIENCES**

**M. Pharm. (Second Semester) EXAMINATION**

**MAY/JUNE, 2022**

**(CBCS PCI)**

**PHARMACEUTICAL MANUFACTURING TECHNOLOGY**

**MQA204T**

**(Tuesday, 02-8-2022)**

**Time : 2.00 p.m. to 5.45 p.m.**

*Time— 3.45 Hours*

*Maximum Marks—75*

*N.B. :- (i) All questions are compulsory.*

*(ii) Answer to the point only.*

*(iii) Figures to the right indicate full marks.*

1. Solve the following questions :

20

- (a) What is sterilization in place (SIP) ?
- (b) What is formulation by design ?
- (c) Enlist in process quality control tests for suspension ?
- (d) What is QTTP ?
- (e) State ICH guidelines.
- (f) Write a note on drug plastic interaction.
- (g) What is QbD ?
- (h) What is process automation in pharmaceutical industry ?
- (i) Write in brief about Form Fill Seal (FFS) technology.
- (j) Give application of fluidized bed technology.

P.T.O.

2. Answer any *two* of the following : 2×10=20

- (a) Explain lyophilization technology in detail.
- (b) Discuss in details about containers and closures used for pharmaceuticals.
- (c) Discuss process automation in pharma industries for granulation and pelletization processes.

3. Solve any *seven* of the following : 7×5=35

- (a) Give the quality control test for emulsion and suspension.
- (b) Describe the legal requirement during developing a pharmaceutical industry. What are the factors influencing plant location ?
- (c) Discuss in detail about Cleaning In Place (CIP).
- (d) How stability of pharmaceutical packaging material is evaluated ?
- (e) Give the principle of aseptic process technology.
- (f) Discuss in detail the QbD approach for excipients.
- (g) Discuss in detail factors affecting plant layout.
- (h) Discuss in detail various tools of Process Analytical Technology (PAT).
- (i) Discuss the problems encountered in coating process.

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**PQ—03—2022**

**FACULTY OF SCIENCE & TECHNOLOGY**

**M. Pharm. (First Year) (Second Semester) EXAMINATION**

**MAY/JUNE, 2022**

**HAZARDS & SAFETY MANAGEMENT**

(MQA-201T)

**(Tuesday, 26-07-2022)**

**Time : 02.00 p.m. to 05.45 p.m.**

*Time— 3.45 Hours*

*Maximum Marks—75*

*N.B. :— (i) All questions are compulsory.*

*(ii) Answer to the point only*

*(iii) Figures to the right indicate full marks.*

1. Solve all the following : 2×10=20

(a) Give the objectives of Factory Act and Rules.

(b) Enlist the sources of air based hazards.

(c) What are the risk associated with sulphonation ?

(d) Enlist the renewable and non-renewable sources of energy.

(e) Give the functions of ecosystem.

(f) What is preliminary hazard analysis ?

(g) Mention the types of fire extinguishers.

(h) What is TLV ? Mention its significance.

(i) Enlist the hazard based on radioisotopes.

(j) Give the objectives of critical training for risk management.

2. Solve any *two* of the following : 10×2=20

(a) Discuss in detail about air circulation maintenance for sterile area and non-sterile area in industry.

P.T.O.

- (b) Discuss in detail about source and controlling measures of chemical hazards.
  - (c) Discuss about energy resources and land resources and problem associated with it.
3. Solve any *seven* of the following :
- (a) Write a note on ICH guidelines for risk assessment and management.
  - (b) Discuss various management tools to control over exposure to chemicals.
  - (c) What is the relief system and proofing system in prevention and protection of fire.
  - (d) Write in brief about management of combustible and toxic gases.
  - (e) Write a note on critical training for risk management.
  - (f) Discuss in brief about multiphase reaction, transport effect and global rates under fire and explosion.
  - (g) Write a note on natural resources.
  - (h) Write a note on air based hazards.
  - (i) Discuss about role of emergency services in hazards management.