MIP 202 T

Total No. of Questions : 14] [Total No.of Pages : 01

M. PHARMACY DEGREE EXAMINATIONS, JULY - 2022

Second Semester

INDUSTRIAL PHARMACY

SCALE UP AND TECHNOLOGY TRANSFER

Time : **Three Hours** Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x5 = 25 M**

1. Discuss the objectives and significance of Pilot Plant Design.
2. Illustrate the SUPAC guidelines.
3. What is scale up ? Add a note on steps in scale up.
4. What are the things to consider with scale up in R & D Pharma ?
5. Discuss the need of pharmaceutical validation.
6. Brief out the rapid mixer granulator equipment qualification.
7. Explain the documents used in validation.

SECTION - B

Answer any FIVE Questions. **5x10 = 50 M**

8. How to get start the pilot plant design ? What does a pilot plant cost and what steps are involved with respect to pharmaceutical dosage forms ?
9. Explain pilot plant scale up considerations for solids.
10. Draw the layout of the relationship between different activities during technology transfers from the pilot plant to the production facility. Explain in detail.
11. Write an elaborated essay about IQ, OQ and PQ of DHS.
12. Why vendor qualification is important and how vendor qualification works ? Explain.
13. Who should do equipment validation ? Explain the validation of tablet compressior machine.
14. Explain the test functions and acceptance criteria of performance qualification.

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Total No. of Questions : 14] [Total No.of Pages : 02

M. PHARMACY (REGULAR) DEGREE EXAMINATIONS, JANUARY-2022

Second Semester

INDUSTRIAL PHARMACY

SCALE UP AND TECHNOLOGY TRANSFER

Time : **Three Hours** Maximum : 75 Marks

SECTION - A

Answer any FIVE Questions. **5x5 = 25 M**

1. Discuss in detail concept and importance of scale up techniques.
2. What is vendor qualification ? Briefly discuss the parameters that should be taken into consideration for this purpose.
3. Explain in detail about equipment validation process for autoclave and fluidized bed drier.
4. Explain development phase of technology transfer from RKD to production for capsules.
5. Distinguish prospective, retrospective and concurrent validations.
6. What is "re-qualification" ? Mention the reasons for requalification and methods used for this purpose.
7. Discuss the need and methods used for effluent treatment in a pharmaceutical plant.

SECTION - B

Answer any FIVE Questions. **5x10 = 50 M**

8. Draw the flow chart of technology transfer in pharmaceutical industry and discuss in detail about scale up process for liquid orals.
9. Explain cleaning validation. Discuss the factors influencing cleaning validation.
10. Discuss installation, operational and performance qualifications for rapid mixer granulator.

11. Explain

    a) Requirements for a semi-solid formulation unit.

    b) OQ for double cone blender.

12. a) How are the water process systems validated ? Explain in detail.

    b) Discuss the general principles for pharmaceutical water systems.

13. Explain in detail about the pilot plant design of tablets.

14. Define industrial hazards. Explain different types of fire extinguishers.

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M.PHARMACY (Supple) DEGREE EXAMINATIONS, FEB/MAR-2020

Second Semester

M.PHARMACY

INDUSTRIAL PHARMACY

SCALE UP AND TECHNOLOGY TRANSFER

Time: Three Hours

Maximum marks:75

SECTION-A

Answer any FIVE Questions 5X5=25M

1. Give plant layout and facilities for the production of Parenterals.
2. What is validation protocol? Write a note on cleaning validation.
3. Discuss 1Q, 0Q, PQ for autoclave.
4. Define Process validation? Write a note on validation of liquid filling and sealing.
5. Define Hazards and discuss about pharmaceutical hazards with their preventive measures.
6. Outline the objectives of scaleup techniques and discuss the problems encountered during technology transfer.
7. What is VMF? Add a note on Vender Qualification.

SECTION-B

Answer any FIVE Questions 5X10=50M

8. Write the siginificance and requirements of Pilot plant scaleup studies? Discuss scaleup studies for semisolid preparations.
9. Discuss indetail various parameters involved in analytical method validation.
10. What is Equipment Qualification? Discuss how to perform equipment qualification for HPLC.

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11. Explain about different types of validation. Discuss the process validation involved in tablet coating.

12. What are various types of hazards and discuss about fire and electrical hazards with their safety measures.

13. Define qualification of equipment and classify. Write about aseptic room validation.

14. What is Vendor Qualification. Explain about documentation and manufacturing records involved in technology transfer.