Exam Date & Time: 03-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES END SEMESTER THEORY EXAMINATIONS - MAY 2018 PROGRAM: MPHARM SEMESTER 2 (INDUSTRIAL PHARMACY)

> DATE: 03/05/2018 TIME: 02:00 PM - 5:00 PM

Scale-up and Technology Transfer [PCE-MIP202T]

Marks: 50 Duration: 180 mins.

a Answer all the questions. Answer the following (5 marks \times 8 = 40 marks) Discuss on processing equipment selection in pilot plant scale up. 1) (5)Explain the critical parameters to be considered in scale up of capsule filling and 2) (5)quality control tests to evaluate the same. 3) Explain the method to determine Biological oxygen demand in effluent. (5) Discuss on preventive measures for electrical hazards in pharmaceutical industry. 4) (5)5) List out the documents required while qualifying a new API vendor. Briefly give the importance of facility audit of vendor. (5) Write a short note on cleaning validation and state the acceptance criterions as per 6) FDA standards. (5) What is Performance Qualification? List out the important acceptance criterions in 7) PQ. (5)Define material safety data sheets (MSDS). Give the procedure for using MSDS. 8) (5) b

Answer all the questions.

Answer the following with specific answers (2 marks \times 5 = 10 marks)

9) Mention the types of process validation.

(2)

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A)		
B)	Mention the evaluation tests to be carried during validation of tablet coating phase.	(0
(C)	Explain sealing evaluation test for parenterals.	(2,
D)	State the differences between protocol and report with a specimen format.	(2)
		(2)
E)	Write a brief note on Hearing protection in pharmaceuticals.	(2)
End		

m Date & Time: 07-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES END SEMESTER THEORY EXAMINATIONS - MAY 2018 PROGRAM: MPHARM SEMESTER 2 (INDUSTRIAL PHARMACY)

DATE: 07/05/2018 TIME: 02:00 PM - 5:00 PM

Pharmaceutical Production Technology [PCE-MIP203T]

Marks: 50

Duration: 180 mins. a Answer all the questions. Answer the following (5 marks \times 8 = 40 marks) Explain the principle of microfluidizer technology with the help of diagram. 1) (5)2) Explain any two microencapsulation techniques. (5)3) Explain the working of fluidized bed spray granulator. (5)Explain the principle involved in super critical fluid processor. 4) (5)5) Discuss the different types of glass used in pharmaceutical industries. (5)Define hard gelatin capsule. Write the steps involved in manufacturing of empty 6) capsules. (5) 7) Discuss environmental control zone grouping in parenteral production. (5) 8) Define and enlist different dust collectors. Explain the working principle of single cyclone separator. (5)b Answer all the questions. Answer the following with specific answers (2 marks x = 10 marks) 9) Write any four applications of lyophilisation process. (2)A)

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- B) What are the causes of blistering in tablets?
- C) Enlist any two advantages and disadvantages of spray drying process.
- D) Give the difficulties associated with filling of capsules with pellets.
- E) Why antiscalant and coagulant are used in water treatment? (2)

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