

SVKM'S NMIMS

Shobhaben Pratapbhai Patel / School of Pharmacy & Technology Management

Programme: M. Pharm / M. Pharm + MBA (Pharmaceutics)

Year: I

Semester: I

Academic Year: 2019-20

Marks: 75

Subject: Modern Pharmaceutics

Time: 2.00 pm to 5.00 pm

Duration: 3 hrs.

Date: 22 November 2019

No. of Pages : 2

FINAL EXAMINATION

Instructions: Candidates should read carefully the instructions printed on the question paper and on the cover of the Answer Book, which is provided for their use.

- 1) Question No. 1 is compulsory (5 Questions of 3 marks each)
- 2) Out of remaining questions, attempt any 4 questions.(15 marks each)
- 3) In all 5 questions to be attempted (Compulsory).
- 4) Answer to each new question to be started on a fresh page.
- 5) Figures in brackets on the right hand side indicate full marks.
- 6) Assume suitable data if necessary.

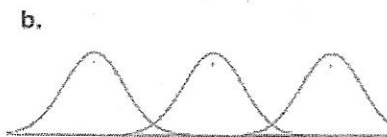
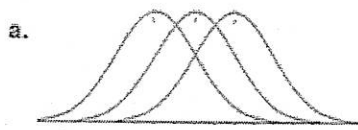
Section A

(Attempt All Questions)

Q.1

[15]

- i. Fill in the blanks from: Consolidation time, Contact time, Dwell time, Peak offset time
 - a. _____ time is the time to reach maximum force.
 - b. _____ time is the time at which maximum displacement occurs.
 - c. _____ time is the time for compression and decompression.
- ii. How does validation differ from qualification?
- iii. Match the following three discriminations considering distribution of three samples showing "Between Group Variability"



- i. Discrimination between only two groups, but not the third
- ii. Little discrimination
- iii. Some discrimination
- iv. Large discrimination

- iv True/False? Justify
CGMPs require that forced degradation studies always be conducted of the drug product when the routes of degradation and the suitability of the analytical procedures can be determined through use of alternate procedures.
- v Fill in the blanks:
In Heckel's plot, there is proportionality between _____ with the pressure in a process kinetics. In this case the _____ were the reactant and _____ the product.

Section B

- Q.2. A. With proper diagram show how is force balance done in a die during tablet compression [5]
B. Enlist the four major factors affecting the dissolution process. In brief explain the different factors related to the dissolution testing device. [5]
C. What is a Chi Square Test? What does the "Goodness of fit" statistic in chi-square test measures? [5]
- Q.3 A. List out the different approaches to industrial relations. In brief explain the unitary and the system approach. [5]
B. What are the factors affecting sales forecasting? [5]
C. Write short note on the steps involved in Students T-test and ANOVA. [5]
- Q.4 A. What is validation master plan? which factors are considered in VMP? [5]
B. Compare and contrast zero base budget, incremental and Open ended Budget. [5]
C. How is validation of a fluidized bed dryer done? In brief explain all important aspects. [5]
- Q.5 A. What are factorial designs? Enumerate its advantages and applications with suitable examples. What are the applications of DoE studies in formulation development? [10]
B. In what cases the fractional factorial designs are used? In brief discuss the concept of confounding in factorial designs. [5]
- Q.6 A. In brief explain the theories of compaction and compression. Describe in detail the 4 stages of compression cycle and the effect of applied forces on compression in tablets. [10]
B. What are the different factors affecting degree of volume reduction in compaction of tablets? Briefly discuss all important points. [5]
- Q.7 A. What are CGMPs? How does FDA determine if a company is complying with CGMP regulations? How would a new drug company learn about CGMPs to comply with them? [10]
B. Briefly discuss the implication of concept of significance and Standard deviation in pharmaceutical statistics. [5]

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