

Birla Institute of Technology and Science, Pilani (Rajasthan)
First Semester (2022-23)
PHA F413: Pharmaceutical Management and Quality Control
Mid Semester Examination (Closed Book)

Duration: 1 hour 30 min

Max. Marks: 25

*Give proper explanation wherever is required to answer the questions.
Please do not share any information with your classmates during the Test.*

Q.1. (A) Give a brief description of the procedure followed in heat distribution study conducted for an autoclave. Why it is necessary to be conducted?

(B) What is the role of biological indicator in sterility validation?

[2.0+0.5+1.0=3.5 M]

Q.2. (A) "Inventory control and management is relevant for only those organizations which have low capital."

Do you agree with the above statement? Give proper justification in support of your answer.

(B) Discuss various types of inventory categories?

[3+2 = 5.0 M]

Q.3. (A) Enlist essential components (any six) required to be present in documentation of batch production and control records.

(B) In which conditions salvaging operations of drug products may be conducted?

[3+2=5.0 M]

Q.4. (A) Give a brief description of the validation of raw materials for a tablet manufacturing unit?

(B) What are the various advantages of employing Design of experiments as a tool in QbD.

[4+2.0= 6.0 M]

Q.5. (A) What are the various categories of variations observed in manufacturing organizations?

(B) Give a brief description of different causes of variations exhibited in a manufacturing organization.

[1.5+4.0 = 5.5 M]

All the Best