

Birla Institute of Technology and Science, Pilani (Rajasthan)
First Semester (2023-24)

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) A proper written procedure is established and followed for the cleaning and maintenance of equipment used in manufacturing of pharmaceutical products. Provide six aspects required to be included in the written procedure.

(B) Give a brief description of the written testing program designed to evaluate stability characteristics of drug products.

[3.0+3.0 = 6.0 M]

Q.2. (A) What do you mean by decimal point reduction time? Briefly describe the essential aspects of the validation of a tunnel sterilizer.

(B) Give a brief explanation of four important in-process tests involved in the validation of production of tablet dosage forms.

[(1+4) +4 = 9.0 M]

Q.3. Establish the control charts for *X-bar* and *R* for the following data:

Sample	Subgroups			
	X1	X2	X3	X4
1	12	11	9	7
2	13	11	10	7
3	14	12	9	8
4	7	13	12	10
5	13	12	9	6

[6.0 M]

Q.4. Explain the following with respect to the validation of an analytical method used in a pharmaceutical industry-

(a) Specificity and sensitivity (b) Precision

[1+3 = 4.0 M]

All the Best