

Birla Institute of Technology and Science, Pilani (Rajasthan)

First Semester (2023-24)

PHA F413: Pharmaceutical Management and Quality Control

Comprehensive Examination (Closed Book)

Duration: 2 hours

Max. Marks: 30

Give proper explanation wherever is required to answer the questions.

Q.1. (A) Inventory management is an integral part of a manufacturing organization. Why? Give four different reasons in your answer.

(B) How selective inventory control helps in effective inventory management? Give proper explanation using suitable examples.

[2+3=5.0 M]

Q.2. (A) Why validation of a product or process is important for a pharmaceutical manufacturing organizations? Give brief explanation with suitable examples.

(B) Give a brief description (six) of the general requirements as per CGMP regulations for building and facilities used for a drug product manufacturing.

[3+3= 6.0 M]

Q.3. (A) Briefly describe various factors affecting plant layout of a pharmaceutical organization.

(B) Using a schematic diagram, briefly explain the Centre storage and perimeter production type of plant layout.

[3+3=6.0 M]

Q.4. What do you mean by break-even analysis? How is it calculated? What are the drawbacks of break-even analysis?

[1+1+2=4.0 M]

Q.5. Why statistical quality control is a very important aspect in quality management of pharmaceutical products? Give an explanation of the utility of *X-bar* and *R-* control charts in quality management of tablets using tablet weight and tablet thickness as examples. **[2+4=6.0 M]**

Q.6. Briefly explain various components of marketing mix?

[3.0 M]

All the Best

Birla Institute of Technology and Science, Pilani (Rajasthan)

First Semester (2023-24)

PHA F413: Pharmaceutical Management and Quality Control

Comprehensive Examination (Open Book)

Duration: 1 hour

Max. Marks: 15

Give proper explanation wherever is required to answer the questions.

Q.1. (A) What is the rationale of testing (i) In vitro dissolution of tablets and (ii) Moisture content of dried granules during validation of a tablet dosage form?

(B) Using a schematic diagram briefly explain a proper sampling techniques required to be followed for an effective checking of blend uniformity of the tablet granules.

[4+2=6.0 M]

Q.2. (A) Give a brief explanation (with suitable examples) of the following aspects in improving sales of a product-

(i) After sales services (ii) Acquisition of an organization

(B) “Cold spot is a variable point of a particular type of autoclave.”

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

[3+3=6.0 M]

Q.3. Why estimation of depreciation cost of equipment and building facilities are crucial for smooth running of an industry? Give detailed explanation in support of your answer.

[3.0 M]

All the Best