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BRAINWARE UNIVERSITY

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Brainware University
398, Ramkrishnapur Road, Barasat
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Term End Examination 2025-2026
Programme – B.Pharm-2020/B.Pharm-2021/B.Pharm-2022
Course Name – Industrial Pharmacy II - Theory/Industrial Pharmacy II
Course Code - BP702T
(Semester VII)

Full Marks : 75 **Time : 3:0 Hours**

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A
(Multiple Choice Type Question) 1 x 20=20

1. *Choose the correct alternative from the following :*

(i) Select the process that involves increasing the batch size.
a) Batch incrimination
b) Size enlargement
c) Scale up
d) None of the these

(ii) Which one of the following is multifunctional processor for granulation?
a) FBD
b) Sigma blade mixer
c) Planetary mixer
d) RMG

(iii) What are the meaning of 5Ms?
a) Money, material, man, manufacturing & machine
b) Money, magnitude, man, method & machine
c) Money, material, man, method & machine
d) Made, material, man, method & machine

(iv) Select the ICH secretariat is based in_____.
a) Geneva
b) Bern
c) Zurich
d) Austria

(v) Identify the appropriate term for wide-ranging concept covering all matters that individually or collectively influence the quality of a product.
a) Quality assurance
b) Process validation
c) Quality control
d) Research and development

(vi) Identify the correct option which defines a documented evidence that provides a high degree of assurance on a specific process to consistently give result in a product that meets its predetermined specifications and quality characteristics.
a) Quality assurance
b) Process validation
c) Quality control
d) Research and development

(vii) Select the defining term for the transfer of technology between sites of the same group of companies.
a) Inter company transfer
b) Intra company transfer
c) In process control transfer
d) Finished product transfer

(viii) Identify the part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

a) Gap analysis
b) Drug master file
c) Good manufacturing practices
d) Inter company transfer

(ix) Select the exact term for the multidimensional combination and interaction of input variables (e.g. material attributes) and process parameters that have been demonstrated to provide assurance of quality.

a) Design space
b) Design qualification
c) Acceptable criteria
d) Change control

(x) Identify the step at which control can be applied and is essential to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.

a) CAPA
b) Acceptable criteria
c) Critical control point
d) Change control

(xi) Identify the large scale apparatus or a full size plant among the following.

a) Prototype
b) Pilot plant
c) Scale-up plant
d) Production department

(xii) Choose the correct answer of multifunctional processor for granulation?

a) FBD
b) Sigma blade mixer
c) Planetary mixer
d) RMG

(xiii) Choose the correct option, what is the primary focus of phase 3 clinical testing.

a) How to manage costs
b) The collection and analysis of highly specific efficacy end-point data
c) The optimal range of effective dosage
d) The analysis of data results from the small-subset target population

(xiv) Choose the correct answer, which two criteria does the FDA classify NDAs.

a) Novelty of the active ingredient and time to market
b) Balance between safety and effectiveness
c) Novelty of the active ingredient and clinical improvement
d) Clinical improvement and effectiveness of product

(xv) Choose from the following those drugs that are available to consumers without a prescription.

a) Old drug products
b) New drug products
c) OTC drug products
d) None of these

(xvi) Choose for biological products are approved for marketing under the provisions of the _____.

a) Code of federal regulation
b) Public hospital service act
c) Civil federal regulations
d) Public health service act

(xvii) State in pilot plant technique personnel should have.

a) Experience in pilot plant to operations as well as in actual production area
b) Should understand intent of the formula or as well as understand the perspective of the production
c) Should have some engineering knowledge
d) All of these

(xviii) Select the correct option, the pilot plant administration and information processing area should have space for meeting of _____.

a) 8-10 people
b) 3-4 people
c) 10-20 people
d) All of these

(xix) In which area physical testing equipment place in pilot plant?

a) Administration and information processing
b) Storage area
c) Physical testing area
d) Standard equipment floor space

(xx) What is the objective of FDA Indian office?

a) Manufacture of drugs in USA for the purpose of export to India
b) Approval of medical products for marketing in India

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c) To ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States

d) Import of drug in India for test and examination

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Illustrate the term of the following - DRA,CDSCO,DCGI,DTAB,DCC,CDTL,COPP,GMP,ICH and ISO. (5)
3. Briefly explain the concept of technology transfer. (5)
4. Explain the roles and responsibilities of RA personnel. (5)
5. Explain the importance of TQM in pharmaceutical industry handling. (5)
6. List the considerations for scaling up the pilot plant for liquid orals. (5)
7. Illustrate the function of CDSCO. (5)

OR

Illustrate a short note on approval of new drug in India. (5)

8. Explain in details national accreditation board for testing and calibration laboratories(NABL). (5)

OR

Explain of a brief note on DCGI. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Describe in detail of the pharmaceutical platform technology and their uses. (10)
10. Explain in details NABI and GLP. (10)

OR

Explain about out of specification(OOS) and briefly discuss the investigation on OOS results. (10)

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