BRAINWARE UNIVERSITY

Term End Examination 2024-2025
Programme – B.Pharm-2019/B.Pharm-2020/B.Pharm-2021
Course Name – Industrial Pharmacy II/Industrial Pharmacy II - Theory
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 which of the following is not a scale-up process.
a) Laboratory to pilot-scale
b) Pilot-scale to industrial-scale
c) Industrial to pilot-scale
d) Laboratory to industrial-scale

(ii) Which one of the following is space requirement for pilot-plant scale up studies?
a) Administration area
b) Physical testing area
c) Storage area
d) All of the these

(iii) What is multiple of batch size at stage of pilot scale?
a) Multiple of 10X
b) Multiple of 100X
c) Multiple of 1000X
d) None of the these

(iv) Select the full form of NDA is _____.
a) New Drug Application
b) New Dose Application
c) Novel Drug Application
d) Imperial New Dossier

(v) Which statement is correct?
a) Process with small equipment will not develop scale up
b) In too big equipment will not develop scale up
c) Process with large and small both equipment will not develpe scale up
d) Process with small equipment will develop scale up

(vi) Installation qualification or IQ , define as.
a) A documented verification of the proposed design of the facilities, systems and equipments
b) Evidence of all key aspects of the process equipment and ancillary system installation

c) Objective evidence process for the control limits and action levels in product of all predetermined requirements

d) Verifying a process, under anticipated condition, consistently produces a product, which meets all predetermined requirements

(vii) Select the correct option which defines quality control.

a) Sampling and documentation
b) Sampling, specification and documentation
c) Sampling, specification, testing, documentation and release procedures
d) None of these

(viii) Select the pharmacovigilance is a part of_____.

a) ICH E1 guidelines
b) ICH E2 guidelines
c) ICH E3 guidelines
d) ICH E2 (A-F) guidelines

(ix) Select the correct purpose of technology transfer in pharmaceutical industry.

a) Develop dosage form
b) Provide efficiency in process
c) Maintain quality of product
d) All of the these

(x) Tell the invention idea, technology prototype or scale up product development is a part of_____.

a) Pilot scale up technique
b) Commercial batch scale
c) Analytical method transfer
d) Technology transfer

(xi) Identify the correct option which describes the procedure of technology transfer.

a) Scientifical
b) Analytical
c) Logical
d) Modificational

(xii) Select the correct full forms of SU & RU in case of technology transfer in the pharmaceutical industry.

a) Scientific unit & research unit
b) Sending unit & receiving unit
c) Straight unit & round unit
d) Solar unit & roster unit

(xiii) Select the appropriate term for the identification of critical elements of a process which are available at the SU but are missing from the RU.

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

(xiv) Predict the pilot plant can be used for.

a) Evaluating results for laboratory studies
b) Product and process correction
c) Shelf life and stabilities studies
d) All of these

(xv) 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

(xvi) Identify the parameters that are required to optimize process of blending.

a) Time of blending
b) Blender loading
c) Size of blender
d) All of the these

(xvii) Predict at the end of the study, what happens to the case report forms (CRFs)?

a) The CRF data is compiled and submitted to the FDA in the IND
b) The CRF data is aggregated by an external party if the trial was double blinded to assess the drug's safety and efficacy
c) The CRF data is aggregated and analyzed to assess the drug's safety and efficacy
d) The CRF data is compiled and submitted to Regulatory Affairs

(xviii) Identify for variation approval timeline for II type of variation as per EU guideline is_____.

a) 30- 90 days
b) 150- 180 days
c) 210 days
d) 120 days

(xix) Logical procedure that controls the transfer of any process together with its documentation and professional expertise between manufacture sites.

a) Regulation Procedure
b) Technology transfer
c) CAPA
d) Technology Modification

(xx) Select the full form of MoU.

a) Memorandum of Understanding
b) Memorandum of University
c) Memorandum of Uniformity
d) None of these

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. Describe about the different phases of clinical trial. (5)
4. Write a note on investigator's brochure (IB). (5)
5. Explain the importance of TQM in pharmaceutical industry handling. (5)
6. Discuss the importance of granularity of technology transfer concerning API, excipients, finished products and packaging materials. (5)
7. Explain short note on certificate of pharmaceutical product (COPP). (5)

OR

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

8. Illustrate the term QbD along with its objective and significance. (5)

OR

Illustrate the function of CDSCO. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Explain the principles and entire process of quality risk management in the process of transfer of technology of pharmaceutical industry. (10)
10. Explain about out of specification(OOS) and briefly discuss the investigation on OOS results. (10)

OR

Explain about new drug application along with explain in details stages of drug approval process in India. (10)

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