BRAINWARE UNIVERSITY

Term End Examination 2023
Programme – B.Pharm-2019
Course Name – 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) Who are the study leaders based at each site during the clinical trial?

a) Chief medical officer and clinical research associates.
b) Principal investigators and study coordinates
c) Study coordinates and chief medical officer
d) Principal investigators and clinical research associates

(ii) 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

(iii) On 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

(iv) Full form of CTD is

a) Common Technical Document
b) Critical Technical Document
c) Critical Technical Dossier
d) Common Technical Dossier

(v) 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

(vi) The ---------is the means through which the sponsor technically obtains this exemption from the FDA

a) AND
b) AIND
c) INDA
d) IND

(vii) What does the expansion in CRO's reflect?

a) A pharma company's desire to balance control over drug development with fluctuations in workload
b) The pharma company trying to reduce its fixed investment in development by buying CROs
c) The desire to reduce competition with smaller biotech companies
d) A desire for the pharma companies to build their in-house development capability

(viii) The full form of IND is

a) Investigational New Drug
b) Investigational New Dossier
c) Imperial New Drug
d) Imperial New Dossier

(ix) What does the expansion in CRO's reflect?

a) A pharma company's desire to balance control over drug development with fluctuations in workload
b) The pharma company trying to reduce its fixed investment in development by buying CROs
c) The desire to reduce competition with smaller biotech companies
d) A desire for the pharma companies to build their in-house development capability

(x) What does the expansion in CRO's reflect?

a) A pharma company's desire to balance control over drug development with fluctuations in workload
b) The pharma company trying to reduce its fixed investment in development by buying CROs
c) The desire to reduce competition with smaller biotech companies
d) A desire for the pharma companies to build their in-house development capability

(xi) Which of the following methods are generally used in liquid filling?

a) Gravimetric
b) Volumetric
c) Constant level method
d) All the these

(xii) Process of increasing the batch size is called

a) Batch incrimination
b) Size enlargement
c) Scale up
d) None of the these

(xiii) What does the expansion in CRO's reflect?

a) A pharma company's desire to balance control over drug development with fluctuations in workload
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(xiv) Select 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

(xv) A large scale apparatus or a full size plant is called as

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

(xvi) Parameters that are required to optimize process of blending includes

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

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

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

(xviii) ----------are those drugs that are available to consumers without a prescription.

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

(xix) As per SUPAC , the change which is not having significant impact on product performance and quality is known as

a) Level 1 changes
b) Level 0 changes
c) Level 2 changes
d) Level 3 changes

(xx) 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

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Write a note on Drug development team and their functions. (5)

OR

What are the benefits of TQM? (5)

3. What are the principles of TQM? (5)

OR

What are the advantages and disadvantages of TQM? (5)

4. What are the WHO guidelines for technology transfer (5)

OR

What do you know about CDTL? (5)

5. Define plant, pilot plant and scale up. (5)

OR

Write a note on Investigator's Brochure (IB). (5)

6. Write down the different stages of technology transfer (5)

OR

Discuss regulatory authorities and their responsibilities. (5)

7. What are the responsibilities of central authorities? (5)

OR

What is Technology transfer (5)

8. What is the function of CDSCO in central? (5)

OR

What do you mean by QRM (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. What kind of application can be submitted as a 505(b)(2) application? What are the examples of changes to approved drug products for which 505(b)(2) application should be submitted ? What is a Marketing Authorization Application? What are the differences between NDA and 505 (b)(2) application ? (10)

OR

i. What is State drug control organization? ii. What is SDRAs iii. What is the Function of State Licensing Authorities? iv. What are the Responsibilities of State Authority? (10)

10. Who are the members of DTAB? (10)

OR

i. What is QbD? ii. What are the advantages of QbD? iii. What are the objectives of QbD? iv. What are the key aspects of QbD? (10)

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