BRAINWARE UNIVERSITY

Term End Examination 2022
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) Animal studies, clinical trials, bioavailability studies are part of which application process

a) IND b) NDA
c) BLA d) ANDA

(ii) 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

(iii) 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

(iv) List of approved drugs and their associated IPR is available in

a) Red book b) Orange book
c) Pink book d) Black book

(v) Variations that are the minor variations which have only a minimal impact or no impact at all, on the quality, safety or efficacy of the medicinal product are called as

a) Type IA variation b) Type IB variation
c) Type II variation d) Extension applications

(vi) Which is the responsibility/s of RA personnel

a) To analyze the content of the active ingredient in the formulation b) Work with federal, state and local governing agencies to get the approval for drug
c) To undertake stability studies of the drug products d) To supervise the production of the formulation

(vii) In pilot scale up in process evaluation parameter(s) involve

a) Order of mixing b) Mixing speed and time
c) Heating cooling rates d) All of these

(viii) 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

(ix) Logical procedure that controls the transfer of any process together with its documentation and professional expertise between developments or between manufacture sites- Known as

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

(x) Full form of CTD is

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

(xi) The main aim of cGMP procedure include

a) Equipment qualification and process validation
b) Regular process review and revalidation
c) Use of competent, technically qualified personnel
d) All of these

(xii) 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

(xiii) 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

(xiv) Stability testing comes under

a) Quality guidelines
b) Safety guidelines
c) Efficacy guidelines
d) All of the these

(xv) The full form of IND is

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

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

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

(xvii) Process of increasing the batch size is called

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

(xviii) In pilot plant in space requirement forth area is

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

(xix) The headquarter of the WTO is located at

a) Austria
b) Belgium
c) Czech
d) Geneva

(xx) Relevant processing equipment should not be too big or small because

a) Process with small equipment will not develop scale up
b) In too big equipment will not develop scale up
c) Both
d) None of these

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Give an overview on typical QRM process (5)

OR

What is the function of CDTL? (5)

3. What do you know about DCGI? (5)

OR

What is the purpose of SUPAC guidelines? (5)

4. What do you mean by risk identification, risk analysis, risk evaluation, risk control, risk education (5)

OR

What do you mean by TQM? (5)

5. What is GMP consideration? What is the significance of pilot plant? (5)

OR

What are the characteristics of TQM? (5)

6. Discuss the role and responsibilities of RA professional. (5)

OR

What is the importance of TQM in pharmaceutical industry handling? (5)

7. Why conduct pilot plant studies? What is SUPAC? (5)

OR

What are the objectives and significance of pilot plants? (5)

8. Discuss the different phase of clinical trial. (5)

OR

Write a note on Non-clinical drug development process. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. i. What do you mean by OOS? ii. What is the investigation of OOS results? (10)

OR

i. What is Six Sigma? ii. What are the characteristics of Six Sigma? iii. What are the objectives of Six Sigma? iv. What are the methodologies of Six Sigma? (10)

10. Discuss general consideration of Investigational New drug Application. (10)

OR

What is a New Drug Application? What is an Abbreviated New Drug Application (ANDA)? What is a DMF? What are the types of DMFs? (10)

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