BRAINWARE UNIVERSITY

Term End Examination 2023-2024
Programme – B.Pharm-2019/B.Pharm-2020
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 one of the following is multifunctional processor for granulation
a) FBD b) Sigma blade mixer
c) Planetary mixer d) RMG

(ii) Out of the following functions of compression process, select which one is optional
a) Pre-compression b) Filling of empty die cavity
c) Compression of granules d) Ejection of tablets

(iii) State Full form of cGMP is
a) Current great manufacturing practices b) Current good manufacturing practices
c) Current good manufacturing procedure d) None of these

(iv) Tell The main aim of production rate consideration is
a) To maintain quality with speed b) Only to increase profit
c) To decrease labor cost d) None of these

(v) Predict What is the purpose of the case report form
a) To ensure data accuracy by providing a place to store warehouse patient data for audit purposes b) To provide a reference for all study subjects from which to analyze patient data
c) To include in the NDA filing d) All of these

(vi) cGMP regulations for pharmaceutical manufacturing comes under which organization domain of US FDA, choose the correct one
a) Center for Biologics Evaluation and Research b) Center for Drug Evaluation and Research (CDER)
c) Office of Regulatory Affairs (ORA) d) Center for Food Safety and Applied Nutrition

(vii) Select the correct one, Copyright is granted for

a) Pharmaceutical product
b) Radio isotopes
c) Logo
d) Music and Literature

(viii) Choose the correct answer,The oldest quality control laboratory of the Drug Control Authorities in India is

a) Central Drugs Testing Laboratory, Kolkata
b) Central Drugs Testing Laboratory, Chennai, Tamil Nadu
c) Central Drugs Testing Laboratory, Hyderabad, AP
d) Central Drugs Testing Laboratory, Mumbai

(ix) Write at the end of the study, what happens to the case report forms

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

(x) 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

(xi) The federal register act was amended in which year to provide a "codification" of all regulations every five years known as code of federal regulations. Choose the correct one

a) 1936
b) 1937
c) 1938
d) 1939

(xii) Write the full form of CFR is----------

a) Code of federal rules
b) Civil federal regulations
c) Code of federal regulations
d) Civil federal rules

(xiii) Predict in pharmacovigilance the term ADR stands for _____

a) Absolute Drug Reaction
b) Adverse Drug Reaction
c) Adverse Dose Reaction
d) Absolute Dose Reaction

(xiv) Select the correct answer,Drug regulatory agency of country Australia is...

a) TGA
b) MCC
c) MHRA
d) ANVISA

(xv) Select the ICH Secretariat is based in.....

a) Geneva
b) Bern
c) Zurich
d) Austria

(xvi) Select which of the following terms ICH guidelines include

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

(xvii) Select the Full form of R & D department is

a) Record and development
b) Rate and design
c) Research and development
d) None of these

(xviii) 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

(xix) select the filling method of a pharmaceutical liquid depends on the following factors

a) Viscosity of the liquid
b) Surface tension of the liquid
c) Compatibility with the material used in the construction of the filling machine
d) All the these

(xx) Tell which the process of increasing the batch size is called

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

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Briefly explain the concept of technology transfer. (5)
3. Describe the WHO guidelines for technology transfer in pharmaceutical industry (5)
4. Explain the principles and significance of Quality Risk Management. (5)
5. Explain the role of regulatory requirements approval procedure for new drugs. (5)
6. Contrast a short note on approval of new drug in India. (5)
7. Contrast the function of CDSCO in centre. (5)

OR

Explain short note on Certificate of Pharmaceutical Product (COPP). (5)

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

OR

Explain in details National Accreditation Board for Testing and Calibration Laboratories(NABL). (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Summarize in detail the principles and significance of documentation in technology transfer emphasizing on confidentiality agreement, licensing, MoUs and legal issues with examples (10)
10. Explain in details NABl and GLP (10)

OR

Explain on the organization of CDSCO along with in details on Ex-officio, nominated & elected members of Drug Technical Advisory Board and their functions. (10)

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