BRAINWARE UNIVERSITY

ODD Semester Examinations 2021- 22

Programme – Bachelor of Pharmacy - 2018 [B.Pharm]

Course Name – Industrial Pharmacy II

Course Code – BP702T

(Semester VII)

Time allotted : 1 Hour 30 Minutes | Full Marks : 75

(Multiple choise type question) | 75 x 1 = 75

Choose the correct alternative from the following

(I) Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results known as

A) a. Quality assurance
B) b. Qualification
C) c. Process validation
D) d. Quality control

(II) The involved disciplines at an organization where a designated product, process or method is expected to be transferred from

A) a. QA
B) b. SU
C) c. RU
D) d. TQM

(III) Objective of pilot plant is/are

A) Find mistakes on small scale and make profit on large scale
B) To produce physically and chemically stable form
C) To identify the critical features of the process
D) All of the these

(IV) 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

(V) Which of the following is a part of 4 M's of quality manufacturing

A) Modeling
B) Machine
C) Mechanism
D) Manufacturing

(VI) Transfer of technology done by the

A) a. Trained and knowledgeable person
B) b. Junior analysts
C) c. Any person from R&D department
D) d. Any person from production department

(VII) _____ covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished products conform with established specifications for identity, strength, purity and other characteristics

A) a. Quality assurance
B) b. Process validation
C) c. Quality control
D) d. Research and development

(VIII) Inspection, scrap and repair are examples of _____

A) a. Internal costs
B) b. External costs
C) c. Cost of dissatisfaction
D) d. Societal costs

(IX) A 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 is known as

A) a. CAPA
B) b. Acceptable criteria
C) c. Critical control point
D) d. Change control

(X) A 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

(XI) 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

(XII) Inspection is a part of the _____

A) a. Quality assurance and quality control

B) b. Quality planning

C) c. Quality improvement

D) d. Quality circle

(XIII) According to Deming's most of the problems are related to systems and it is the responsibility of the management to improve the systems

A) a. Correct

B) b. Correct to some extent

C) c. Correct to great extent

D) d. Tagucchi

(XIV) 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

(XV) Identification of critical elements of a process , are available at the SU but are missing from the RU

A) a. Gap analysis

B) b. Drug master file

C) c. Inter company transfer

D) d. Good manufacturing practices

(XVI) Documented evidence that the premises, supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of good manufacturing practices (GMP) is known as

A) a. CAPA

B) b. Design qualification

C) c. Acceptable criteria

D) d. Change control

(XVII) ICH guidelines include

A) Quality

B) Safety

C) Efficacy

D) All of these

(XVIII) The transfer of technology could happen in following ways

A) a. Government labs to private sector firms

B) b. Between private sector firms of same country

C) b. Between private sector firms of different country

D) c. All of the options

(XIX) Following is exempted from ROW countries

A) Canada

B) Europe

C) New Zealand

D) All of these

(XX) Documented verification that the system or subsystem performs as intended over all anticipated operating ranges known as

A) a. Identification qualification

B) b. Installation qualification

C) c. Performance qualification

D) d. Operational qualification

(XXI) ICH Secretariat is based in…….

A) Geneva

B) Bern

C) Zurich

D) Austria

(XXII) A transfer of technology between sites of different companies

A) a. Gap analysis

B) b. Drug master file

C) c. Good manufacturing practices

D) d. Inter company transfer

(XXIII) Quality practices must be carried out _____

A) a. At the start of the project

B) b. Throughout the life of the project

C) c. At the end of the project

D) d. No need to carry out quality practices

(XXIV) Invention idea and technology feasibility – prototype or scale up – product development – initial manufacture – commercialization these are all the steps of

A) a. Pilot scale up technique

B) b. Commercial batch scale

C) c. Analytical method transfer

D) d. Technology transfer

(XXV) 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

(XXVI) In pilot plant administration and information processing area should have space for meet of

A) 8-10 people
B) 3-4 people
C) 10-20 people
D) All of these

(XXVII) GeM stands for

A) Government Money
B) Government e-marketing
C) Government e-marketing Place
D) Goods e-marketing Place

(XXVIII) The federal register act was amended in ----------to provide a “codification” of all regulations every five years known as code of federal regulations.

A) 1936
B) 1937
C) 1938
D) 1939

(XXIX) 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

(XXX) Assured quality is necessary for building customer confidence

A) a. Correct
B) b. Correct to some extent
C) c. Correct to great extent
D) d. incorrect

(XXXI) Clinical studies come under

A) Quality guidelines
B) Safety guidelines
C) Efficacy guidelines
D) All of these

(XXXII) ----------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

(XXXIII) General considerations for pilot plant to scale up techniques are

A) Reporting responsibilities, personnel requirements, space requirements
B) Review formula, equipment production rates
C) Process evaluation, preparing of master manufacturing procedure, GMP consideration
D) All of these

(XXXIV) According to TQM computer systems should be designed and operated to

A) a. Maintain the regularity
B) b. To keep the daily data
C) c. Prevent unauthorized entries or changes to the programme
D) d. All of the three

(XXXV) 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

(XXXVI) Followings are the principle of TQM except

A) a. Produce quality work the first time and every time
B) b. Focus on the customer
C) c. No requirements of proper strategic approach to improvement
D) d. Improve continuously

(XXXVII) 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

(XXXVIII) A set of principles that provides a framework within which laboratory studies are planned performed, monitored, and archived and reported is known as

A) a. GDP
B) b. GLP
C) c. GMP
D) d. cGMP

(XXXIX) Technology transfer is helpful to

A) a. Develop dosage form
B) b. Provide efficiency in process
C) c. Maintain quality of product
D) d. All of the options

(XL) Animal studies, clinical trials, bioavailability studies are part of which application process

A) IND
B) NDA
C) BLA
D) ANDA

(XLI) The full form of IND is

A) Investigational New Drug
B) Investigational New Dossier
C) Imperial New Drug
D) Imperial New Dossier

(XLII) On which two criteria does the FDA classify NDAs

A) Novelty of the active ingredient and clinical improvement
B) Novelty of the active ingredient and time to market
C) Balance between safety and effectiveness
D) Clinical improvement and effectiveness of product

(XLIII) In case of technology transfer there is a proper SU and RU, what is the full form of SU & RU

A) a. Scientific unit & research unit
B) b. Sending unit & receiving unit
C) c. Straight unit & round unit
D) d. Solar unit & roster unit

(XLIV) Pharmacovigilance is a part of

A) ICH E1 guidelines
B) ICH E2 guidelines
C) ICH E3 guidelines
D) ICH E2 (A-F) guidelines

(XLV) A transfer of technology between sites of the same group of companies known as

A) a. Inter company transfer
B) b. Intra company transfer
C) c. In process control transfer
D) d. Finished product transfer

(XLVI) According to BCS classification for Class III drugs is

A) High solubility high permeability
B) Low solubility Low permeability
C) High solubility low permeability
D) Low solubility high permeability

(XLVII) Drug regulatory agency of country Australia-----

A) TGA
B) MCC
C) MHRA
D) ANVISA

(XLVIII) 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

(XLIX) “Quality is defined by the customers” is

A) a. An unrealistic definition of quality
B) b. A user-based definition of quality
C) c. A manufactured based definition-based quality
D) d. A product-based definition of quality

(L) What are the 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

(LI) Installation Qualification or IQ is

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

(LII) Detailed information concerning a specific facility, process or product submitted to the drug regulatory authority, intended for the incorporation into the application for marketing authorization known as

A) a. Gap analysis
B) b. Drug master file
C) c. Inter company transfer
D) d. Good manufacturing practices

(LIII) All of the following costs are likely to decrease as a result of better quality except

A) a. Customer dissatisfaction cost
B) b. Inspection costs
C) c. Maintenance costs
D) d. Warranty and service costs

(LIV) Identify the relevant regulatory body in USFDA for approval of drugs

A) CDER
B) CBER
C) BLA
D) IND

(LV) Followings are the benefits of TQM except

A) a. Improved quality
B) b. No employee participation
C) c. Team work
D) d. Working relationships

(LVI) 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

(LVII) Advantages of TQM

A) a. Improves reputation
B) b. Higher employee morale
C) c. Lower cost
D) d. All of the three

(LVIII) Process of increasing the batch size is called

A) Batch incrimination
B) Size enlargement
C) Scale up
D) None of the thses

(LIX) Important steps involved in scale up are

A) Conducting laboratory studies
B) Rate controlling steps adjustment
C) Design and construct a pilot plant
D) All of these

(LX) In the event Which unit identifies particular problems with the process during the transfer

A) a. Sending unit
B) b. Receiving unit
C) c. Both
D) d. No unit involve in this matter

(LXI) Full form of CTD is

A) Common Technical Document
B) Critical Technical Document
C) Critical Technical Dossier
D) Common Technical Dossier

(LXII) For successful transfer, the following general principles and requirements should be met

A) a. The project plan should encompass the quality aspects of the project
B) b. The capabilities of the SU and the RU should be similar, but not necessarily identical
C) c. A comprehensive technical gap analysis between the SU and RU including technical risk assessment and potential regulatory gaps, should be performed as needed
D) d. All the options

(LXIII) Quality trilogy includes

A) a. Quality planning
B) b. Quality improvement
C) c. Quality control
D) d. All of three

(LXIV) In pilot plant physical testing equipment(balance, pH meter)place in which area

A) Administration and information processing
B) Storage area
C) Physical testing area
D) Standard equipment floor space

(LXV) TQM stands for

A) a. Turbid quality master file
B) b. Ten quality management
C) c. Total quality management
D) d. None

(LXVI) All medicines sold in South Africa must be registered by ……..…...

A) TGA
B) MCC
C) MHRA
D) ANVISA

(LXVII) 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

(LXVIII) Copyright is granted for

A) Pharmaceutical product
B) Radio isotopes
C) Logo
D) Music and Literature

(LXIX) Importance of pilot plant are

A) Examination of formulae
B) Production rate adjustment
C) Idea about physical space required
D) All of these

(LXX) Full form of ANDA is ----------
A) Abbreviated new drug application
B) Abbreviated new dose application
C) Abbreviated novel drug application
D) None of these

(LXXI) ASMF full form
A) Active substance master file
B) Assessment of substance master file
C) Active substance master formula
D) Assessment of substance main formula

(LXXII) What is the purpose of GLP
A) a. GLP is to certify that every step of the analysis is valid or Not.
B) b. Assure the quality & integrity of data submitted to FDA in support of the safety of regulated products.
C) c. GLPs have heavy emphasis on data recording, record & specimen retention.
D) d. All of the three

(LXXIII) Which of the following is patentable as per Indian patent act
A) New pharmaceutical drug products
B) Naturally occurring substances/elements
C) Plants and animals other than µ-organisms
D) Diagnostic, therapeutic and surgical methods of treatment of humans or animals

(LXXIV) Deming's 4 step cycle for improvement is_____
A) a. Plan, do, check, act
B) b. Schedule, do, act, check
C) c. Do, act, check, monitor
D) d. Plan, control, act, sustain

(LXXV) Elements of quality management system are _____
A) a. Organizational structure
B) b. Responsibilities
C) c. Procedures
D) d. All the three