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341752(41)

B. Pharmacy (Seventh Semester) Examination, April-May/Nov.-Dec. 2020

(PCI Scheme)

INDUSTRIAL PHARMACY THEORY

(BP702T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Read all the instruction carefully given in part I, II and III.*

Part-I

(Multiple Choice Questions) **20×1=20**

Note : *Attempt all the questions. Each question carries 1 mark.*

1. Choose the correct answer :

(i) The part of pharmaceutical industry where a lab scale formula is transformed into a viable product by development of reliable practical method of manufacture is called :

(a) Scale up

(b) Pilot plant

(c) Production

(d) All of these

(ii) The space required in pilot is divided into :

(a) Administration and information area

(b) Physical testing area

(c) Standard equipment and floor space

(d) All of these

(iii) The full name of SUPAC is :

(a) Scale up and postapproval changes

(b) Scale up and preapproval changes

(c) Sale up present changes

(d) None of these

(iv) 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

(v) Which of the following is not the step in technology transfer process?

(a) Research phase

(b) Control phase

(c) Development phase

(d) Production phase

(vi) The product name along with its strength , generic name, MFC number, effective date, shelf life, market, packaging details, are given in :

(a) Master formula card

(b) Master packaging card

(c) Master formula

(d) Specifications and standard test procedure

(vii) The transfer of technology between sites of different companies is called as :

(a) Inter-company transfer

(b) Intra-company transfer

(c) Technology transfer

(d) Technology transfer protocol

(viii) National Research Development Corporation (NRDC) was established in India by the Government of India in :

(a) 1953

(b) 1970

(c) 1980

(d) 1990

(ix) CTD is divded into ..... modules.

(a) 3

(b) 4

(c) 5

(d) 6

(x) Which of the responsibility's of regulatory affair 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

(xi) What is the primary focus of Phase III clinical testing?

(a) How to manage costs?

(b) To generate data regarding the efficacy and safety of the drug

(c) The optimal range of effective dosage.

(d) The analysis of data results from the small-subset target population

(xii) The guidelines for good manufacturing practice in India is :

(a) 21CFR Part 4

(b) Scheduling M

(c) 21CFR Part 211

(d) Eudralex Volume 4

(xiii) The part of a quality system covering the manufacture and testing of pharmaceutical dosage forms or drugs and active pharmaceutical ingredients, diagnostics, pharmaceutical products and medical devices is called :

(a) Good manufacturing practice (GMP)

(b) Good regulatory practice (GRP)

(c) Good clinical practice (GCP)

(d) Good laboratory practice (GLP)

(xiv) Which of the following was developed by Bill Smith to improve its processes by minimizing defects?

(a) ISO

(b) Continuous improvement

(c) Six sigma

(d) Quality control

(xv) Which of the following concerned about quality for achievement of TQM?

(a) The Managing Director

(b) The Operative

(c) The Quality Manager

(d) Everyone in the organization

(xvi) The objective of ISO-9000 family of quality management is :

(a) Customer satisfaction

(b) Employee satisfaction

(c) Skill enhancement

(d) Environmental issues

(xvii) Central Drugs Standard Control Organisation regulates pharmaceutical and medical devices. Who is the head of CDSCO?

(a) Drug Controller General of India

(b) Auditor General of India

(c) Chief Medical Officer

(d) None of these

(xviii) Where is the headquarter of CDSCO present?

(a) New Delhi

(b) Mumbai

(c) Kolkata

(d) Hydrabad

(xix) Full name of NABL is :

(a) National Accreditation Board for Testing and Calibration Laboratories

(b) National Affiliation Board for Lab Equipment

(c) National Associated Board for Lab Test

(d) None of these

(xx) The following is considered as a division of CDCSO :

(a) Clinical trails

(b) Biologicals

(c) DCC-DTAB

(d) All of these

Part-II

(Long Answer Type Questions) **2×10=20**

Note : *Attempt any* ***two*** *questions. Each question carries 10 marks.*

2. Write about significance of personnel requirement in pilot plant scale up technique. Discuss pilot plant scale up technique for solid dosage form.

3. Explain technology transfer protocol and technology transfer from R & D to production.

4. Discuss responsibility of regulatory affairs professionals. Write in details about Investigational New Drug (IND) application process.

Part-III

(Short Answer Type Questions) **7×5=35**

Note : *Attempt any* ***seven*** *questions. Each question carries 5 marks.*

5. Discuss SUPAC guidance.

6. Describe validation in technology transfer process.

7. Explain new drug application for drug approval process.

8. Discuss GLP in details.

9. Write note on quality by design.

10. Discuss clinical research protocols for drug approval process.

11. Describe total quality management system.

12. Explain organization and responsibility of CDSCO.

13. Discuss six sigma as quality management system in pharmaceutical industry.