Total No. of printed pages = 4

BP 804 ET

Roll No. of candidate | | | | | | | | | | |

2023

B.Pharm. 8th Semester (Regular) End-Term Examination

PHARMACEUTIAL REGULATORY SCIENCE THEORY

New Regulation (w.e.f. 2017-18)

Full Marks – 75 Time – Three hours

The figures in the margin indicate full marks for the questions.

1. Answer *all* the questions : (20 × 1 = 20)

(i) Name the type of NDA application that needs to be filed in United States for combination of two or more active moieties ————————

(a) Type 2 (b) Type 4

(c) Type 5 (d) Type 6

(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) ASMF stands for ————————

(a) Active substance master file

(b) Assessment of substance master file

(c) Active substance master formula

(d) Assessment of substance main formula

(iv) Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in

(a) US market (b) Europe market

(c) Canadian market (d) All countries

(v) Quality by design (QbD) is a concept introduced by the international conference on harmonization (ICH) as _____guideline.

(a) ICH Q5 (b) ICH Q6

(c) ICH Q7 (d) ICH Q8

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(vi) The guideline ICH Q1A (R2) refers to

(a) Stability study of new molecular entities and associated drug products

(b) Generation of photostability information

(c) Analytical validation

(d) Impurities

(vii) In PCT, patent application enters national phase at ————————

(a) 12 months (b) 24 months

(c) 30 months (d) 36 months

(viii) The entry in Batch Manufacturing Record is done by ————————

(a) Quality control department

(b) Quality assurance department

(c) Warehouse department

(d) Production department

(ix) The objective of FDA- India office is ————————

(a) To ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States

(b) Approval of medical products for marketing in India

(c) Import of drug in India for test and examination

(d) Manufacture of drugs in USA for the purpose of export to India

(x) BCS classification for Class III drugs is ————————

(a) High solubility high permeability

(b) Low solubility high permeability

(c) High solubility low permeability

(d) Low solubility Low permeability

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

(a) BLA (b) IND

(c) CBER (d) CDER

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

(a) Pink book (b) Orange book

(c) Red book (d) Black book

(xiii) How many drugs can be imported under single Form 11 license?

(a) 20 (b) 5

(c) 10 (d) 15

(xiv) A competitor can file for ANDA before its expiry under ———— clause of ANDA certification clause.

(a) Para I (b) Para II

(c) Para III (d) Para IV

(xv) CFR stands for ————

(a) Code of Federal Regulations

(b) Centre of Federal Regulations

(c) Code of Federal Register

(d) Centre of Federal Regulator

(xvi) The headquarter of the WTO is located at ————

(a) Geneva (b) Belgium

(c) Austria (d) Czech

(xvii) The initiation of ICH took place with representatives of regulatory agencies of _____ to discuss the wider implications and terms of reference.

(a) Japan, Australia, US (b) US, Europe, India

(c) US, Europe, Japan (d) Europe, Australia, US

(xviii) Type I DMF deals with ————

(a) Packaging materials (b) Manufacturing Site

(c) Drug substance (d) Excipients

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

(a) IND (b) NDA

(c) ANDA (d) BLA

(xx) cGMP regulations for pharmaceutical manufacturing comes under which organization domain of US FDA ————

(a) Center for Biologics Evaluation and Research

(b) Center for Food Safety and Applied Nutrition

(c) Office of Regulatory Affairs (ORA)

(d) Center for Drug Evaluation and Research (CDER)

2. Answer any *seven* (7 × 5 = 35)

(a) Describe the contents of investigator brochure used in clinical studies.

(b) Discuss about regulatory requirements for Generic drug approval process.

(c) Describe general cheek list for 21 CFR part 11.

(d) Explain the approval process for implementing the changes to an approved NDA.

(e) Explain the Drug Master File.

(f) Explain the Orange Book features.

(g) Discuss about Organization structure and Overview of regulatory authorities of India.

(h) Difference between NDA and ANDA.

(i) Explain the preclinical studies involved in drug discovery

3. Answer any *two* : (2 × 10 = 20)

(a) Write short notes on (4 × 2.5 = 10)

(i) Phase II clinical trials

(ii) Exclusion criteria in clinical trials

(iii) Informed consent form

(iv) Institutional Review Board

(b) Define the term TGA and EMEA. Enlist the functions of TGA.

(c) Explain the design in developing clinical trial protocols. Explain the approval process of timeline involved in Investigational New Drug.