10-06-19

Total No. of printed pages = 7

MPH 203T

Roll No. of candidate

2019

M.Pharm. 2nd Semester End-Term Examination

COMPUTER AIDED DRUG DELIVERY SYSTEM (CADD)

New Regulation (w.e.f. 2017-2018)

Full Marks – 75 Time – Three hours

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

1. Answer any *fifteen* questions. (15 × 1 = 15)

(i) _____ is called the first real success of structure-based drug design.

(a) Aspirin
(b) Captopril
(c) Losartan
(d) None of the above

(ii) Da Vinci XI is a type of

(a) Drug discovery robot
(b) Surgical robot
(c) Diagnosis robot
(d) Spraying robot

[Turn over

(iii) Intelligence composed of following components

(a) Reasoning, Learning, Problem Solving, Perception, Linguistic Intelligence

(b) Reasoning, Learning, Problem Solving and Perception

(c) Reasoning, Learning, Problem Solving and Linguistic Intelligence

(d) Reasoning, Learning, Perception and Linguistic Intelligence

(iv) The domain of Artificial Intelligence is classified into

(a) Formal tasks and Mundane tasks

(b) Mundane tasks and Expert tasks

(c) Formal tasks and Expert tasks

(d) Formal tasks, Mundane tasks and Expert tasks

(v) The following model is used in computer simulation for pharmacokinetic and pharmacodynamic studies

(a) In-silico model

(b) NON-LIN

(c) MEDLINE

(d) None of the above

(vi) Quality risk management guidelines are specified in

(a) ICH Q8

(b) ICH Q9

(c) ICH Q10

(d) ICH Q11

(vii) A dynamic model that represents GI tract physiology is

(a) ROSETTA

(b) Q-SITEFINDER

(c) SimCYP

(d) ASAPprime

(viii) Eligibility for biowaiver consideration in case of BCS class II drugs is

(a) Dose-to-solubility ratio 250 and high permeability with 85% absorbed

(b) Similar or rapid/very rapid dissolution of test and reference product

(c) Very rapidly dissolving

(d) Drug dissolves completely during GI passage

(ix) The following simulation model interactions is used to predict clinically important drug-drug interactions

(a) Gastro-Plus

(b) SimCYP™

(c) NON-MEM

(d) MKMODEL

(x) SWISS-MODEL is a type of

(a) Carbohydrate structure

(b) Lipid structure

(c) Protein structure

(d) None of the above

(xi) The following points should be considered before selecting any software for Experimental Designs and Optimization techniques

(a) A simple graphic user interface (GUI) that's intuitive and easy-to-use

(b) A well-written manual with tutorials to get you off to a quick start

(c) A wide selection of designs for screening and optimizing processes or product formulations

(d) All of the above

(xii) A full factorial design has ——————.

(a) 2^k run

(b) 3^k run

(c) 5^k run

(d) 9^k run

(xiii) When planning a clinical trial, the following factor is considered while selecting an appropriate statistical design:

(a) Number of treatments to be compared

(b) Availability of experimental units: subjects or patients

(c) Inter-subject and intra-subject variabilities

(d) All of the above

(xiv) ———————— design is usually a preferred choice in case of five or more factors.

(a) Box Design

(b) Taguchi design

(c) Plackett-Burman

(d) CCD

(xv) FDA guidance provides total ———————— numbers of biowaivers for scale up or post approval changes of drug application.

(a) 07

(b) 05

(c) 04

(d) 03

2. Answer any *eight* questions : (8 × 5 = 40)

(a) Outline the difference between ligand based and structure based CADD.

(b) What are the factors to be considered in developing an in-vitro-invivo correlation for drug development?

(c) Write in brief the history in use of computer in pharmaceutical research and development.

(d) Outline the status of enforcement of Intellectual Property Rights in R & D investors in India.

(e) Discuss the protocols followed in clinical data management (CDM) process.

(f) Write a short note on descriptive vs mechanistic modeling.

(g) What is process optimization? Write the important features of full factorial design and central composite design.

(h) Explain different data collection approaches that are commonly utilized in carrying out clinical public health and translational research.

(i) Outline the benefit of Design of Experiments (DOE). What are the types of DOE commonly used in pharmaceutical product optimization?

(j) Give the significance of in-silico pharmaco-kinetic modeling.

(k) How optimal design is helpful in estimation of population parameters? Explain with suitable example.

3. Answer any *two* out of *three* : $(2 \times 10 = 20)$

(a) What is artificial Neural Network (ANN)? Discuss briefly its types with examples. Explain in brief the role of Robot Scientist and artificial Intelligence in drug product development. $(1 + 2 + 2 + 5 = 10)$

(b) Outline the difference between current and QbD approach to pharmaceutical development. Write the benefit of implementation of QbD by FDA to pharmaceutical industries. Outline the steps involved in Quality by Design (QbD) process development. Enlist the target product quality profile of immediate release tablet as per QbD concept. $(2 + 3 + 3 + 2 = 10)$

(c) (i) What is clinical data management systems, which are used to manage the data collected during clinical trials? Write the applications of various clinical data management software's.

(ii) Explain in detail various qualitative and quantitative In-Silico models for studying the drug disposition. What are the important descriptors of BBB permeability?

(5 + 5 = 10)