Total No. of printed pages = 4

MPH 203T

Roll No. of candidate ☐☐☐☐☐☐☐☐☐☐

2020

M.Pharm. 2nd Semester End-Term Examination

COMPUTER AIDED DRUG DELIVERY SYSTEM

Full Marks – 75

Time – Three hours

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

SECTION — A

1. Multiple Choice questions.

(10 × 1 = 10)

(i) Fuzzy Logic (FL) is a method of reasoning that involves:

(a) Digital value Yes

(b) Digital value Yes and NO

(c) Digital value NO

(d) None of the above

(ii) Quality risk management guidelines are specified in

(a) ICH Q8

(b) ICH Q9

(c) ICH Q10

(d) ICH Q11

(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) A dynamic model that represent GI tract physiology is

(a) ROSETTA

(b) Q-SITEFINDER

(c) SimCYP

(d) ASAPprime

(v) Da Vinci XI is a type of:

(a) Drug discovery robot

(b) Surgical robot

(c) Diagnosis robot

(d) Spraying robot.

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(vi) 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

(vii) Virtual trial enables to incorporate data of

    (a) IVIVC

    (b) Literature search

    (c) Inter-subject variability

    (d) Inter-compartment movement of drug

(viii) 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

(ix) The robot-scientist, Eve is designed by:

    (a) Oxford University

    (b) University Of Cambridge and Manchester

    (c) University of California

    (d) Harvard University

(x) ACAT model of human GI tract consists of —————— compartments which are further divided into —————— sub-compartment.

    (a) 5, 10   (b) 4, 8

    (c) 9, 10   (d) 10, 11

2. Write short answer of the following questions.

    (a) What do you mean by Quality-by-design?   (1+ 1+ 1+ 1+ 1)

    (b) Enlist two descriptors for BBB permeability.

    (c) What is non linearity at the optimum?

    (d) What do you mean by medical coding?

    (e) What are the tools of clinical data management?

SECTION — B

(Attempt any four questions. All questions carry 15 marks)

3. (a) Give the significance of *in silico* pharmacokinetic modeling. (2+3+4+6)

   (b) Explain in brief the theoretical background of construction of simulation software package such as GastroPlus.

   (c) What are the input parameters in a ACAT model? Discuss the simulation of fed and fasted state in an *in silico* model.

   (d) Outline the FDA, EMA and WHO guidelines for biowaiver consideration? Discuss the computer aided modeling and establishing of *in vitro-in vivo* correlation.

4. (a) What are the major responsibilities of clinical data management (CDM) team? What are the regulatory guidelines and Standards in CDM? (5+5+5)

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

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

5. Explain any 3 (three) of the following (5+5+5)

   (a) Descriptive Vs mechanistic modeling

   (b) Population modeling

   (c) *In silico* models for drug disposition

   (d) Statistical parameters

6. (a) Enlist some commercially available softwares for ADMET. (3+4+4+4)

   (b) Explain any two endogenous *BBB/BCSF* barrier transporters those can be utilized to deliver therapeutic agents to the brain.

   (c) Give the various approaches and parameters involved in predicting the drug bioavailability by *in silico models*.

   (d) Enlist the important transporters involved in ADMET and suitable *in silico* models to study the transporters.

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(a) Define dependent and independent variable? Write the important features of full factorial design and central composite design. (4+4+4+3)

(b) What is screening design? Outline the distinguishing features of graphical and numerical optimization.

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

(d) Discuss in brief softwares used in optimization process.

(a) What is artificial Neural Network (ANN)? What are its types? (3+4+4+4)

(b) What is Robotics? Outline the basic components of Robot system. Give the difference between Robot and other Artificial Intelligence programme.

(c) What are Agent and Environment in Artificial Intelligence? Write in brief about the characteristics of goal based agents and utility based agents.

(d) Explain in brief the role of Robot Scientist and artificial Intelligence in drug discovery.