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MPH 203T

Roll No. of candidate

2018

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.

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

(a) The robot-scientist, Eve is designed by

(i) Oxford University

(ii) University of Cambridge and Manchester

(iii) University of California

(iv) Harvard University

(b) Da Vinci XI is a type of

(i) Drug discovery robot

(ii) Surgical robot

(iii) Diagnosis robot

(iv) Spraying robot

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(c) Intelligence composed of following components

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

(ii) Reasoning, Learning, Problem Solving and Perception

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

(iv) Reasoning, Learning, Perception and Linguistic Intelligence

(d) The domain of Artificial Intelligence is classified into

(i) Formal tasks and Mundane tasks

(ii) Mundane tasks and Expert tasks

(iii) Formal tasks and Expert tasks

(iv) Formal tasks, Mundane tasks and Expert tasks

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

(i) Digital value Yes

(ii) Digital value Yes and No

(iii) Digital value No

(iv) None of the above

(f) Quality risk management guidelines are specified in

(i) ICH Q8 (ii) ICH Q9

(iii) ICH Q10 (iv) ICH Q11

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

(i) ROSETFA

(ii) Q-SITEFINDER

(iii) SimCYP

(iv) ASAPprime

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

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

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

(iii) Very rapidly dissolving

(iv) Drug dissolves completely during GI passage

(i) Virtual trial enables to incorporate data of

(i) IVIVC

(ii) Literature search

(iii) Inter-subject variability

(iv) Inter-compartment movement of drug

(j) ADAM model consists of

(i) 03 compartments

(ii) 05 compartments

(iii) 07 compartments

(iv) 02 compartments

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

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

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

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

(iv) All of the above

(l) A fill factorial design has

(i) 2^k run (ii) 3^k run

(iii) 5^k run (iv) 9^k run

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

(i) Number of treatments to be compared,

(ii) Availability of experimental units: subjects or patients

(iii) Inter-subject and intra-subject variabilities

(iv) All of the above

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

(i) Box Design

(ii) Taguchi design

(iii) Plackett-Burman

(iv) CCD

(o) The following is not true in QbD concept approach

(i) Specifications based on product performance requirements

(ii) Specifications based on batch history

(iii) Quality built into product and process by design, based on scientific understanding

(iv) Flexible process within design space, allowing continuous improvement

2. Answer any EIGHT questions : $(8 \times 5 = 40)$

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

(b) Write the applications of FUZZY logic in tablet formulation optimization. Why computers are considered as important tool in market analysis?

(c) How do you see Artificial Intelligence as future for Pharmaceutical applications?

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

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

3. Answer any TWO out of Three : $(2 \times 10 = 20)$

(a) What is Artificial Neural Network (ANN)? Discuss briefly its types with examples. Outline the components of Expert System. Write the benefits and limitations of Expert system. Explain in brief the role of Robot Scientist and artificial Intelligence in drug discovery.
$(1 + 2 + 2 + 5 = 10)$

(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) Explain in detail various qualitative and quantitative In-Silico models for studying the drug disposition. Enlist the different descriptors or parameters for evaluation of the drug ADME with the suitable softwares available. What are the important descriptors of BBB permeability? (5 + 3 + 2 = 10)