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HQ—13—2022

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

M.Pharm. (First Year) (First Semester) EXAMINATION

MARCH/APRIL, 2023

MODIFIED RELEASE DRUG DELIVERY SYSTEM

Paper MPH102T

(Saturday, 18-3-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three Hours *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Answer the following : 10×2=20

(*a*) What is Pharmacogenetics ?

(*b*) Define polymers. Give its example.

(*c*) Give the principle of rate controlled drug delivery system.

(*d*) Give the advantages of Gastro-Retentive drug delivery system.

(*e*) What are the barriers of occular DDS ?

(*f*) Give the structure of Skin.

(*g*) Define protein and peptide delivery system.

(*h*) Define vaccine. Give its advantages.

(*i*) Give the principle of MUCO adhesion.

(*j*) Give the importance of penetration enhancers.

P.T.O.

2. Solve any *two* : 2×10=20

(*a*) Explain in detail physiochemical and biological approaches for SR/CR formulation.

(*b*) Define Buccal Drug Delivery System. Explain formulation and evaluation of Buccal Drug Delivery System.

(*c*) Discuss the formulation and evaluation of protein delivery system.

3. Solve any *seven* : 7×5=35

(*a*) Describe the mechanism of drug delivery from SR/CR formulation.

(*b*) Write in brief about categories of patients for personalized medicines.

(*c*) Discuss the enzyme activated DDS.

(*d*) Explain modulated drug delivery system.

(*e*) Discuss the mechanism of drug permeation.

(*f*) Describe different approaches of GRDDS.

(*g*) Write in brief about methods to overcome barriers in occular DDS.

(*h*) Discuss the mucosal and transdermal delivery of vaccine.

(*i*) Explain evaluation test of TDDS.

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HQ—23—2022

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Year) (First Semester) EXAMINATION

MARCH/APRIL, 2023

MODERN PHARMACEUTICS

Paper-MPH-103-T

(Tuesday, 21-03-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time— Three Hours *Maximum Marks—75*

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Answer the following questions : 10×2=20

(*a*) Define preformulation.

(*b*) Write the optimization parameters.

(*c*) Mention about inventory management and control.

(*d*) What are Validation and Calibration ?

(*e*) Define Compression and Compaction.

(*f*) Mention the significance of stability.

(*g*) Give the significance of ANOVA.

(*h*) What are similarity factors ?

(*i*) Define sales forecasting and budget.

(*j*) Give importance of emulsifying agent.

2. Solve any *two* of the following : 2×10=20

(*a*) Define optimization. Explain factorial design.

(*b*) Explain validation of equipments in pharmaceuticals.

(*c*) Describe diffussion and dissolution parameters.

P.T.O.

3. Solve any *seven* of the following : 7×5=35

(*a*) Explain self-emulsifying drug delivery system.

(*b*) Describe concept of total quality management.

(*c*) Write ICH and WHO guidelines for stability study.

(*d*) Describe the linearity concept of significance.

(*e*) Explain Chi-square test and student T-test.

(*f*) Explain physics of tablet compression.

(*g*) Write objectives of preformulation and explain preformulation parameters.

(*h*) Describe Validation and Calibration of Master plan.

(*i*) Mention the effect of moisture content on tablet compression and write significance of solubility in formulation development.

This question paper contains **2** printed pages]

HQ—33—2022

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Year) (First Semester) EXAMINATION

MARCH/APRIL, 2023

PHARMACEUTICS

(Pharmaceutical Regulatory Affair)

(Friday, 24-03-2023) **MPH-104-T** **Time : 2.00 p.m. to 05.00 p.m.**

Time—Three Hours *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

(*iii*) Answer to the point only

1. Answer *all* the following questions : 10×2=20

(*i*) What is a New Drug Application ?

(*ii*) Enlist ICH quality guidelines.

(*iii*) Define GMP and GCP.

(*iv*) Give advantages of GLP.

(*v*) Enlist ICH safety guidelines.

(*vi*) Define the role of institutional review board.

(*vii*) Define code of federal regulation.

(*viii*) What is a New Drug Application ?

(*ix*) Define batch processing record.

(*x*) Enlist the modules in CTD.

P.T.O.

2. Solve any *two* of the following : 2×10=20

(*i*) Explain the organization, structure and responsibilities of drug regulatory agencies in E.U.

(*ii*) Discuss ANDA regulatory approval process.

(*iii*) Explain the ICH guidelines for photo stability testing of new drugs.

3. Solve any *seven* of the following : 7×5=35

(*i*) Enumerate the challenges for non-clinical drug development.

(*ii*) Explain various features of Good Clinical Practices (GCP).

(*iii*) What is GLP ? Describe the general facilities required for non-clinical lab studies.

(*iv*) Explain master formula record in pharmaceuticals.

(*v*) Discuss responsibilities of Regulatory Affairs Professional in Pharmaceutical Industry.

(*vi*) Explain Hatch-Waxman Act.

(*vii*) What is DMF ? Describe its types.

(*viii*) Explain importance of training in pharmaceuticals.

(*ix*) Discuss SUPAC guidelines.