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FB—4—2017

FACULTY OF PHARMACEUTICAL SCIENCES

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

OCTOBER/NOVEMBER, 2017

MODIFIED RELEASE DRUG DELIVERY SYSTEM

Paper MPH-101-T

(Thursday, 23-11-2017) **Time : 10.00 a.m. to 1.00 p.m.**

Time—Three Hours *Maximum Marks—75*

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

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

(*iii*) Illustrate your answers with neat sketches wherever necessary.

(*iv*) Answer to the point only.

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

(*a*) What is principle of active immunization ?

(*b*) Give the classification of CRDDS.

(*c*) Give the role of polymers in ocular drug delivery system.

(*d*) Enlist different grades of HPMC. Write applications of HPMC in MDDS.

(*e*) Write the methods of enhancing bioavailability of drugs across the skin.

(*f*) What is enzyme activated DDS ?

(*g*) What are ideal properties of vaccines ?

(*h*) What is rationale of drug to be formulated as CRDDS ?

(*i*) What is telepharmacy ?

(*j*) Application of ion-exchange drug delivery system.

(*k*) What is pharmacogenetics ? Give its applications ?

(*l*) Classify the rate programmed DDS.

P.T.O.

2×10=20

2. Answer any *two* of the following :

(a) Describe in detail the various approaches by which the gastric transit of dosage form can be delayed. Write their advantages.

(b) Classify and describe various components employed for occular drug delivery.

(c) Enlist the different barriers in protein and peptide drug delivery system. Describe formulation and evaluation of same.

7×5=35

3. Answer any *seven* of the following :

(a) Write a note on Ph activated and enzyme activated drug delivery system.

(b) Write the concept, advantages and disadvantages of transdermal drug delivery system.

(c) Describe the factors affecting design and performance of SRDDS.

(d) Describe mechanism of drug permeation through mucoadhesive drug delivery system.

(e) Describe single shot vaccines.

(f) Write a ntoe on sonophoresis and iontophoresis.

(g) What are the categories of patients for personalized medicines with its development and concept ?

(h) Write a note on customized drug delivery system and bielectric medicine.

(i) What are the advantage of three D printing durg delivery system ? How does Three D Printing work ?

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FB—07—2017

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

NOVEMBER/DECEMBER, 2017

MODERN PHARMACEUTICS

Paper MPH-102T

(Saturday, 25-11-2017) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 *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. Solve any *ten* : 10×2=20

(*a*) What is optimization ?

(*b*) Define solubility.

(*c*) Differentiate between compression and compaction.

(*d*) Enlist the physicochemical studies associated with new drug substance.

(*e*) What is dispersion ?

(*f*) Enlist the merits of validation.

(*g*) What is validation of master plan ?

(*h*) Give the policies of CGMP.

(*i*) Give the significance of Chi-square test.

(*j*) What is consolidation ?

(*k*) Define quality.

(*l*) Differentiate between large volume and small volume parenteral.

P.T.O.

2×10=20

2. Solve any *two* :

(a) Explain factorial design. Discuss the various optimization techniques in pharmaceutical formulation and processing.

(b) Define preformulation studies. Give the importance and significance of preformulation studies.

(c) What is Calibration ? Explain in detail validation of equipments in pharmaceuticals.

7×5=35

3. Solve any *seven* :

(a) Write a note on evaluation test of parenterals.

(b) Explain the concept of T.Q.M.

(c) Give a note on Anova test.

(d) Explain Dissolution and Diffusion parameters.

(e) Explain in brief Drug-Excipient interactions.

(f) Explain linearity concept of significance.

(g) Describe physics of tablet compression.

(h) Write in brief about layout of buildings.

(i) Explain in detail budget and cost control.

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FB—10—2017

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

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

NOVEMBER/DECEMBER, 2017

PHARMACEUTICS

Paper MPH-103T

(Pharmaceutical Regulatory Affair)

(Monday, 27-11-2017) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 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. Solve any *ten* : 10×2=20

(*a*) Give the importance of distribution records.

(*b*) Enlist the modulus in CTD.

(*c*) What is investigational new drug application ?

(*d*) Define role of ethics committee in clinical research.

(*e*) What are the types of patent certification ?

(*f*) Enlist the objective of Hatch Waxman Act.

(*g*) What is IMPD ?

(*h*) What is generic drug module ?

(*i*) Give the importance of training in pharmaceutical industry.

(*j*) Enlist ICH safety guidelines.

(*k*) What is bracketing ?

(*l*) Enlist the contents in batch processing search.

2. Solve any *two* : 2×10=20

(*a*) Describe outsourcing of BA and BE studies to CRO.

(*b*) Explain the regulatory requirement for submitting drug substance product approval in US.

(*c*) Explain DNA regulatory approval process.

P.T.O.

3. Solve any *seven* :

(a) Explain master formula record in pharmaceuticals.

(b) Discuss ICH guideline for photostability testing of new drugs.

(c) What is DMF ? Describe its various types.

(d) Explain post approval changes in product life cycle management.

(e) Describe various phases in clinical trials in drug development.

(f) Explain regulatory requirement for TGA.

(g) Describe regulations for combination products.

(h) Explain various documentation involved in pharmaceutical industry.

(i) Discuss ICH guideline for product development.