[LM 937] MAY 2018 Sub. Code: 2937

M.PHARM. DEGREE EXAMINATION (PCI New regulations 2016) SEMESTER-II BRANCH-I – PHARMACEUTICS – MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

O.P. Code: 262937

Time: Three hours Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Outline the quality by design concept in pharmaceutical product development with respect to International conference on harmonization guidelines.

2. Explain the role of computers in clinical data collection and management.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Describe the different levels of *In-vitro* and *In-vivo* correlation.
- 2. Discuss the role of computers in pharmaceutical formulation.
- 3. Write the benefits of pharmaceutical automation in packaging.
- 4. What is artificial intelligence? Mention its application.
- 5. Mention the role of influx transports with examples.
- 6. Differentiate descriptive Vs mechanistic modeling.
- 7. Explain the computational modeling concept with respect to drug absorption and solubility.

[LN 937] NOVEMBER 2018 Sub. Code: 2937

M.PHARM. DEGREE EXAMINATION (PCI New regulations 2016) SEMESTER-II BRANCH-I – PHARMACEUTICS – MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

O.P. Code: 262937

Time: Three hours Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Enumerate the history of computers in pharmaceutical research & development.

2. Discuss the optimization parameters and different optimization techniques in formulation development.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Mention the regulatory and industrial views on quality by design.
- 2. Write about efflux transporters with suitable examples.
- 3. Describe the use of computers in market analysis.
- 4. What are the bio waiver considerations to be considered to get the exception for *In vivo* studies?
- 5. Write the importance of computer simulation in pharmaco-dynamics.
- 6. Describe the applications of computational fluid dynamics in pharmacy.
- 7. Explain pharmaceutical automation role in dosage form manufacturing.

[LO 937] MAY 2019 Sub. Code: 2937

M.PHARM. DEGREE EXAMINATION (PCI New regulations 2016) SEMESTER-II BRANCH-I — PHARMACEUTICS — MPH

PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

Q.P. Code: 262937

Time: Three hours Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. What is Modeling? Explain Computational Modeling of Drug Disposition.

2. Explain in detail about computer aided formulation development.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Optimal design.
- 2. Discuss: a) QbD b) ICHQ8 Guideline.
- 3. Computers in Market analysis.
- 4. Use of Computers in Biopharmaceutical characterization.
- 5. Biomedical simulations (Pharmacokinetic & Pharmaco dynamic).
- 6. Computers in Clinical development.
- 7. Artificial intelligence and Robotics.

[LP 937] NOVEMBER 2019 Sub. Code: 2937

M.PHARM. DEGREE EXAMINATION (PCI New regulations 2016) SEMESTER-II

BRANCH-I – PHARMACEUTICS – MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

O.P. Code: 262937

Time: Three hours Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. The various statistical modeling in Pharmaceutical Research and Development.

2. The applications of computer in various Intellectual Property Rights of Pharmaceutical R & D.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Computer simulations in Gastro intestinal absorption.
- 2. Common issues of computer ethics in Research and Development.
- 3. Variables and confounding in optimization.
- 4. The role of Nucleoside transporters.
- 5. Robotics and its application in pharmacy.
- 6. Biowaiver considerations.
- 7. Applications of scientifically based QbD.

[LQ 0121] JANUARY 2021 Sub. Code: 2937

(APRIL 2020 EXAM SESSION) M.PHARMACY DEGREE EXAMINATION SEMESTER-II (PCI New regulations 2016) PHARMACEUTICS — MPH

PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM *Q.P. Code : 262937*

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

- 1. The history of computers in Pharmaceutical Research and Development.
- 2. The experimental design in optimization of Pharmaceutical formulations.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Role of P-gp efflux transporter in drug disposition.
- 2. Comparison of the traditional and QbD approach (ICH Q8 guidelines) in Pharmaceutical development.
- 3. Applications of computer in patents.
- 4. Computer simulations in whole organism.
- 5. Pharmaceutical automation in tablet manufacturing.
- 6. Applications of computer aided techniques in development of Pharmaceutical emulsion.
- 7. The benefits of QbD in Industry and regulation bodies.

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2937 (OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER-II (PCI New regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM O.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Discuss in detail about ICH Q 8 guidelines.

2. What is modeling? Elaborate computational modeling of drug disposition.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Descriptive and mechanistic modeling's.
- 2. Computer in market analysis.
- 3. Robotics and its application.
- 4. Bio wavier consideration.
- 5. Computer simulation in gastrointestinal absorption.
- 6. Role of nucleoside transporters in drug disposition.
- 7. Application of scientifically based QbD.

[MPHARM 0122] JANUARY 2022 Sub. Code: 2937 (APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER-II (PCI New regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM Q.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Explain the role of computers in clinical data collection and management.

2. Write in details about the various statistical modeling in pharmaceutical research and development.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Application of scientifically based QbD.
- 2. Role of P-gp efflux transporter in drug disposition.
- 3. Describe different levels of In-vitro and In-vivo correlations.
- 4. Computer simulation in whole organisms.
- 5. What is artificial intelligence? Mention its application.
- 6. Application of factorial design in development of pharmaceutical emulsion.
- 7. Describe biowavier consideration.

[M.PHARM 0922] SEPTEMBER 2022 Sub. Code: 2937 (APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER - II (PCI New regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

Q.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. a) Computer simulation in whole organism and isolated tissues.

b) Explain about statistical modeling.

2. Define optimization. Explain the significance of optimization and factorial design.

II. Write notes on: $(7 \times 5 = 35)$

- 1. ICH Q8 guidelines.
- 2. Modelling techniques for absorption and solubility.
- 3. Active transport.
- 4. Role of computer in Market analysis.
- 5. History of computers in pharmaceutical research and development.
- 6. Add a note on Virtual trial.
- 7. Computational fluid dynamics.

[M.PHARM 0423] APRIL 2023 Sub. Code: 2937 (OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER - II (PCI New regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

Q.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Explain the significance of QbD and regulatory and industrial views of ICHQ8 guidelines.

2. Describe about clinical data collection systems.

II. Write notes on: $(7 \times 5 = 35)$

- 1. Factorial design.
- 2. Statistical modeling.
- 3. Active transport.
- 4. Level of invitro-invivo correlation.
- 5. Applications of Computational fluid dynamics.
- 6. History of computers in pharmacy.
- 7. Applications of artificial intelligence in pharmaceutical industry.

[M.PHARM 0823] AUGUST 2023 Sub. Code: 2937 (APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER - II (PCI New Regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

Q.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Write in detail about Computer Aided Biopharmaceutical characterization in Gastrointestinal absorption simulation.

2. Explain about History of Computers in Pharmaceutical Research and Development.

II. Write notes on $(7 \times 5 = 35)$

- 1. Write about Computational Modeling Techniques of Drug Absorption and solubility.
- 2. Statistical Modeling in Pharmaceutical Research.
- 3. Explain about Optimization Parameters.
- 4. In vitro in vivo correlation.
- 5. Write about Pharmaceutical Automation.
- 6. Current Challenges and Future Directions of Artificial Intelligence.
- 7. Computers in Clinical Data development.

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2937 (OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION SEMESTER - II (PCI New Regulations 2016) PHARMACEUTICS - MPH PAPER III – COMPUTER AIDED DRUG DELIVERY SYSTEM

Q.P. Code: 262937

Time: Three hours Answer ALL Questions Maximum: 75 Marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Write in detail about modeling technique for absorption.

2. What are screening designs? Discuss in detail the development of Micro emulsion by screening design.

II. Write notes on $(7 \times 5 = 35)$

- 1. Industrial views of ICHQ8 guidelines.
- 2. History of computers in pharmacy.
- 3. Statistical modeling.
- 4. Explain the significance of pharmaceutical "Quality by Design" (QbD).
- 5. Artificial intelligence in pharmaceutical industry.
- 6. Clinical data collection systems.
- 7. Parameter sensitivity analysis.