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Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – <<>>

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH (RS & RS2)

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

LONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. What is clinical trial? Explain the various phases, planning and execution of clinical trials.
2. What is audit in clinical trials? Explain the types, process and follow up of audit.
3. Define drug discovery. Explain the various processes involved in the drug development.

ORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Regulatory environment in Europe.

What is informed consent form? Discuss the process of informed consent.

Electronic data capture systems.

Procurement and storage of investigation product.

Roles and responsibilities of investigator.

What is clinical data management? Brief the data transfer and database lock process.

Briefly explain: ICH-Good clinical practice.

Discuss about the essential documents for conducting clinical trial.

ORT ANSWERS **10 x 2 = 20 Marks**

What is human ethical committee?

Define challenges in the implementation of ICH guidelines.

Define new drug application.

What is toxicological approaches in drug development process?

Define site initiation visit.

What is a source document?

Define regulatory authority.

What is safety monitoring in clinical trial?

What is called protocol in clinical study documents?

Define closure of study.

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Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 17-Nov-2022

ne: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH (RS & RS2)

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

NG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain in detail the process of designing study protocol in clinical trials. Add a note on the importance of CRF.

Explain about the clinical data management in clinical trials.

Describe the different stages of drug development process.

ORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Explain about IND and enlist different criteria for investigational new drug application.

Explain about safety monitoring in clinical research.

Explain the role and responsibilities of investigators.

Explain the regulatory system in India.

Explain the inclusion and exclusion criteria for clinical trial.

Explain the role of contact research coordinators.

. Describe about Good clinical practice.

. Explain ethical guidelines in clinical research.

10 x 2 = 20 Marks

ORT ANSWERS

. Define orange book and drug master file.

. Define cross sectional study.

. Define randomization.

. Write any two roles of auditors.

. Define Phase II.

. Define Informed consent form.

. Different dosage forms used in during drug discovery process.

. Define biopharmaceutical classification system.

0. Define quality assurance and quality control.

1. Explain waiver of consent.

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Rajiv Gandhi University of Health Sciences, Karnataka

Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 15-Jun-2022

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH (RS & RS2)

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

ONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Discuss in detail Investigational New Drug (IND) application.
2. Explain in detail the roles and responsibilities of the following as per ICH-GCP guideline a) Investigator b) Clinical research associate c) Regulatory authority
3. Discuss about the different methods of post marketing surveillance.

HORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

1. With schematic representation, discuss integrated drug development process.
2. Explain inclusion and exclusion criteria in selection of clinical trial subjects.
3. Briefly, explain phase 1 and phase 2 clinical trials.
4. Write about safety monitoring in clinical trials.
5. Explain in detail the process of clinical trials for vaccines.
6. Discuss the regulatory environment in USA, Europe and India.
7. Discuss in detail about Institutional Review Board.
8. Write the application of computer in clinical data management.

HORT ANSWERS **10 x 2 = 20 Marks**

1. Define therapeutic index.
2. Clinical trials for fixed dose combinations.
3. Define clinical trial.
4. Differentiate Adverse Drug Reaction (ADR) and Adverse Drug Effect (ADE).
5. Define Ethics.
6. List members of ICH.
7. Define protocol.
8. List global ADR reporting Forms.
9. Explain ANOVA.
10. Expand the following terminologies: IND, DCGI, PvPI, BPO

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Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 12-Nov-2021

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH
Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

LONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Discuss about different methods of post marketing surveillance.
2. Explain the monitoring visits in initiation, conduction and closing of clinical trials.
3. Explain briefly about ANDA submission.

SHORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Role of Eudravigilance in safety monitoring.
5. Role and responsibilities of sponsor in clinical trials.
6. Give an overview of regulatory environment in India.
7. Mention the criteria required for selection and recruitment of study subjects.
8. Write a note on clinical data archive.
9. Explain the role of investigators in clinical trials.
10. Write a note on methods of randomization.
11. Write a note on statistical design in clinical trials.

SHORT ANSWERS **10 x 2 = 20 Marks**

12. Define maximum tolerated dose.
13. Objectives of ICH E6.
14. Define unexpected ADR.
15. Submission of Periodic Safety Update Report (PSUR) in India.
16. Selection and withdrawal of subjects in clinical trials.
17. Role of Clinical Research Coordinator (CRC).
18. Note on centralized and decentralized marketing in EU.
19. Consent for Vulnerable subject.
20. Criteria for unblinding the investigational drug.
21. Regulations for Counterfeit drugs

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10

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 17-Mar-2021

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

LONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Enlist the requirements to conduct clinical trials as per schedule Y.
2. Explain about clinical trials audit and inspection with special emphasis on national regulatory authorities.
3. Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting?

SHORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Discuss about designing of informed consent form for clinical study.
5. Write a note on ICH-GCP guidelines.
6. Explain the different pharmacological action studies in the drug development process.
7. Write a note on case control studies.
8. Comment on the challenges in implementation of ethical guidelines.
9. Write a note on Clinical Research Associate (CRA).
10. Discuss data management and its component.
11. Write a note on Accelerate Approval.

HORT ANSWERS **10 x 2 = 20 Marks**

2. Short note on Helsinki declaration.
3. Factors affecting drug bioavailability.
4. Define single blind method.
5. What is scurvy trail?
6. What are the objectives of phase 2 studies?
7. Ethical issues involved in Genetic Screening.
8. Retrospective study with examples.
9. Significance of drug master file (DMF).
10. Importance of clinical trial registries.
11. Validation of clinical study.

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9

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 04-Jan-2020

me: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

NG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain the different post marketing surveillance methods and explain them.

Explain the ethical guidelines for clinical research.

Describe the various drug characterization techniques during drug development process.

ORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Explain the toxicological approach in drug discovery.

Describe the role of clinical research associate.

Explain the components of data management.

Describe pre-clinical trials.

Explain about elements of informed consent process.

Explain about composition and responsibilities of institutional review board.

Explain the role of sponsor.

Describe about the regulatory system in Europe.

10 x 2 = 20 Marks

ORT ANSWERS

List the critical pharmacokinetic parameters in drug development.

Define human equivalent dose.

Define confidentiality.

Define case control studies.

List the different types of blinding.

Methods to take informed consent in research involving children.

Write any two challenges in the implementation of guidelines.

Define regulatory authority.

Define abbreviated new drug application.

Explain the importance of drug master file.

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8

Rajiv Gandhi University of Health Sciences, Karnataka

ear Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – June-2019

ime: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

NG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain clinical trials and monitoring. Discuss different types of monitoring visits in detail.

Write a note on accelerated approval, fast track and priority review in approval of drugs/vaccine.
Explain in detail the process of designing study protocol in clinical trials. Add a note on importance of CRF.

ORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Write a note on active surveillance in ADR reporting.

Discuss observational studies.

Explain the regulatory aspects of clinical trials for surgical procedures/ medical devices.
Write a note on Quality Assurance (QA) and Quality Control (QC) in clinical data management.

Discuss in detail about institutional review board.

Explain the basic methodologies and study designs of BA/BE studies.
Write about safety monitoring in clinical trials.

Discuss in detail about CDSCO guidelines.

10 x 2 = 20 Marks

ORT ANSWERS

Significance of sub acute toxicity

Note on Nuremberg trials
Explain confidentiality and impartial witness in clinical trials.

List the guidelines and acts that govern the conduct of clinical trials in India.

Advantages of multicentre trails.

Drug labeling requirement in clinical studies.

Clinical trial insurance for trial subjects.
What is subject identification code?

Regulatory requirement for research involving children.

Biopharmaceutical classification of drugs

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7

Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – May 2017

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked

Draw neat, labeled diagrams wherever necessary

ONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Explain briefly about Abbreviated New Drug Application (ANDA) submission.
2. Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting?
3. Discuss the principles of ICH-GCP guidelines.

HORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Enumerate designing of case report form (CRF) with a suitable example.
5. Discuss electronic data processing.
6. Explain the role of Business Process Outsourcing (BPOs) in conducting clinical research in India.
7. Explain the objectives of various phases of clinical trial.
8. Discuss in detail about CDSCO guidelines.
9. Explain the role of clinical trial personnel in premature termination or suspension of a study.
10. Discuss conflict of interest in clinical trials.
11. Write a note on Fast track and Priority review.

10 x 2 = 20 Marks

HORT ANSWERS

1. What are LD50 and ED50?
2. Name the critical pharmacokinetic parameter in drug development
3. Define double blinded method.
4. Role of Uppsala monitoring centre (UMC) in safety monitoring.
5. Components of documentation form.
6. Explain Waiver of consent.
7. Note on 21CFR Part 312.
8. Write a note on cohort studies.
9. Responsibilities of contract research organization
10. Use of placebo in clinical trials

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6

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) Degree Examination – NOV 2016

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH (RS)

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

LONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Describe in detail the components and process of Investigational New Drug Application (INDA).
2. Discuss in detail about CDSCO guidelines.
3. Detail the process of Phase I, Phase II and Phase III of clinical trials.

SHORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Discuss the role and responsibilities of Contract Research Coordinator (CRC).
5. Explain the design of patient informed consent form with a suitable example.
6. Discuss an overview of regulatory environment in USA, Europe and India.
7. Briefly explain the pharmacological and toxicological approach to drug discovery.
8. Explain the ethical guidelines for clinical research.
9. Define safety monitoring. Explain its role in clinical trials.
10. Discuss data management process in clinical trials.
11. Explain the challenges in the implementation of guidelines in clinical research.

SHORT ANSWERS **10 x 2 = 20 Marks**

- Explain the criteria to involve children in conducting clinical research.
- Functions of Drug Control General of India (DCGI).
- Declaration of Helsinki
- Note on CIOMS
- Define case control studies.
- Minimum criteria to report ADR
- Importance of European Clinical Directive
- Define Proof of Concept.
- Note on Non-inferiority clinical study
- List various criterias to classify a serious ADR.

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5

ıjiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Mar 2013

Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain the different stages of drug development process.

Describe the composition & responsibility of IRB.

Discuss the different methods used in post marketing surveillance.

r ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Explain the role of investigators in clinical trial.

Write the ethical principles of clinical research.

Elaborate on patient consent process.

Write a note on pre clinical studies.

What are the regulatory systems in USA?

Explain CRF.

What is IND? Enlist the different criteria for IND application.

Explain the data management in clinical research.

10 x 2 = 20 Marks

r ANSWERS

Randomization

Informed consent

Essential documents for clinical trials

Cross sectional study

Safety monitoring

Biopharmaceutical classification system

Phase II clinical trial

ANDA

Clinical research coordinator

Investigational product

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ajiv Gandhi University of Health Sciences, Karnataka

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V Year Pharma-D (Post Baccalaureate) Degree Examination – Sep 2012

Three Hours

Max. Marks: 70 Marks

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain the ethical guidelines for clinical research

Discuss the different Pharmacological action studies in the drug development process

Write a note on clinical data management in clinical trials

r ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Explain CDSCO guidelines

Explain the phase II clinical trials

Write a note on drug characterization

Discuss about IND application

Role and responsibilities of auditors

Write a note on CRA

What are the different regulatory systems in USA, EUROPE and INDIA

Write a note on challenges in the implementation of ICH guidelines

10 x 2 = 20 Marks

ANSWERS

nformed consent

rotocol

hase IV

omposition of IEC

herapeutic index

embers of ICH

hronic toxicity

ohort studies

afety monitoring

nvestigator

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ajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Feb / Mar 2012

: Three Hours

Max. Marks: 70 Mark:

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Discuss the various drug characterization techniques during drug development process

Discuss the principles of ICH-GCP guidelines

Describe in detail investigational new drug application

T ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Give an overview of the regulatory environment in India

Write a short note on clinical trial design

Explain the design of a Case Report Form with a suitable example

Discuss the pharmacological approaches to drug discovery

Explain responsibilities and compositions of Institutional Review Board (IRB)

Describe pre-clinical trials

What are the elements of an informed consent

Write a short note on Abbreviated New Drug Application

T ANSWERS **10 x 2 = 20 Marks**

Define Human Equivalent Dose (HED). How to convert an animal dose to HED

Classify drugs according to Biopharmaceutical Classification System

What are the in vitro assay methods for predicting PK in drug discovery

Explain randomized clinical trial

Define ADR and ADE

What is the role of a Contract Research Organization

Selection and withdrawal of subjects in clinical trails

Write a short note on toxicological studies

Explain the role of auditors

What are the objectives of phase II study

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ajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Aug / Sep 2011

Three Hours

Max. Marks: 70 Marks

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain a clinical trial protocol as per ICH-GCP guidelines

Briefly explain the pharmacological and toxicological approaches to drug discovery

Describe briefly the various phases of clinical trials. Add a note on methods of post – marketing surveillance

r ESSAYS (Answer any six) **6 x 5 = 30 Marks**

Discuss safety monitoring in clinical trials

Write a note on ANDA submission

Give an overview of the regulatory environment in India

Discuss the drug characterization techniques

Discuss the challenges in the implementation of ethical guidelines

Describe the roles and responsibilities of the investigator as per ICH-GCP guidelines

Explain the design of a patient informed consent form with a suitable example

Discuss CDSCO guidelines

10 x 2 = 20 Marks

ANSWERS

Who sponsors clinical trials

Give the importance of orange book and drug master file

What are the goals of good clinical practice

Name the different types of clinical trials

Explain Biopharmaceutical classification system

Write a short note on informed consent process

What are the different IND types

Write a short note on Cohort studies

Name the critical PK parameters in drug development

Define randomization and unblindings

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ajiv Gandhi University of Health Sciences, Karnataka

fth Year Pharma - D (Post Baccalaureate) Degree Examination – August 2010

Three Hours

Max. Marks: 70 Mark:

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

ESSAYS (Answer any two) **2 x 10 = 20 Marks**

Explain in detail the process of designing study protocol in clinical trials. Add a note on the importance of CRF

Explain the various phases of clinical trials

Discuss the CDSCO guidelines

T ESSAYS (Answer any six) **6 x 5 = 30 Marks**

IND application

Ethical guidelines for individual informed consent

Explain general ethical principles in clinical research

Explain the responsibilities of IRB

Explain the drug characterization in drug discovery

Discuss role and responsibilities contract research coordinator

Explain the role of regulatory authority

Explain safety monitoring in clinical research

ANSWERS **10 x 2 = 20 Marks**

ontract research associate

ohort studies

hase II

reparation of an audit report

linical research regulation in INDIA

reparative termination of clinical trial

herapeutic index

regnant women as research participant

ole of investigator

uality assurance and quality control

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