

PHARMACEUTICAL

FORMULATIONS

ASSIGNMENT

Topic :- PARENTERAL PREPARATIONS

NAME :- DHANYA SHREE. B

Class :- III PHARM. D

PARENTERAL PREPARATIONS

ASSAY OF PARENTERAL:- Assay is performed to quantify the active ingredient in the parenteral preparation according to pharmacopoeia methods. Proper testing helps ensure parenteral products are free of contaminants & contain the correct amount of active pharmaceutical ingredient.

QUALITY CONTROL TESTS FOR PARENTERAL:-

- i) Sterility test
- ii) Clarity test
- iii) Leakage test
- iv) Pyrogen test
- v) Assay test

i) STERILITY TEST:- Test for sterility is done by detecting the presence of viable forms of Bacteria, fungi and yeast.

→ Sterility test must be carried out under strict aseptic conditions in order to avoid accidental contamination of product.

Tests:- a) membrane filtration method

b) Direct inoculation method.

PRINCIPLE :- If bacteria on fungi are placed in a medium which provides nutritive material & water and kept at a favourable temperature, the organism will grow and their presence can be indicated by turbidity in clear medium.

Membrane filtration method :-

- > Filterable aqueous preparations
- > Alcoholic preparations
- > Oily preparation
- > Preparation miscible with or soluble in aqueous or oily.

Direct inoculation method :-

- > Suitable for samples with small volumes
- > Volume of the product is not more than 10% of the volume of the medium.
- > Suitable method for aqueous solutions, oily, liquids, ointments & creams
- > Direct inoculation of the culture medium suitable quantity of the preparation to be examined.

(ii) CLARITY TEST:- Particulate matter is defined as unwanted mobile insoluble matter other than gas bubble present in the product.

→ If the particle size of foreign matter is larger than the size of RBC. It can block the blood vessel.

→ The permit limits of particulate matter as per IP are as follows:-

Particle size in μm [equal to or larger than]	Maximum of particles per ml number.
10	50
25	5
50	Nº1

(iii) LEAKAGE TEST:- The sealed ampoules are subjected to small cracks which occur due to rapid temperature changes or due to mechanical shocks.

Filled & sealed ampoules



Dipped in 1% methylene blue solution



Under negative pressure in vacuum chamber



Vacuum released colored solution enter the ampoule.



Detective sealing

iv) **PYROGEN TEST**:- Fever producing metabolic by products of microbial growth & death.

→ Bacterial pyrogens are called "endotoxins" gram -ve bacteria produce more potent endotoxins than gram +ve bacteria & fungi.

TYPES OF PYROGEN TEST:-

- a) Rabbit test
- b) Limulus amoebocyte lysate [LAL] test

a) **RABBIT TEST**:- Dissolve the substance being examined in or dilute it with a pyrogenic free saline solution.

→ warm the liquid being examined to approx. 38.5°C temp before injection.

→ The volume of injection is VLT 0.5ml/kg & VMT 10ml/kg of body weight.

→ Withhold water during test.

→ Clinical thermometer is inserted into the rectum of rabbit to record body temperature.

→ Normal reading of rectal temperature should be taken prior to the test injection at an interval of half an hour & its mean is calculated - initial temperature.

FACTS OF LALUS AMEOCYTE LYATE [LAL] TEST:-

→ In this method the test solution is combined with a cell lysate from the amoebocyte [blood cells] of horseshoe crab.

→ Any endotoxin that might be present will be coagulated with protein fraction of the amoebocyte & results in the formation of a gel.

✓ ASSAY TEST:-

→ Assay is performed to standardize according to the method given in the monograph of that parenteral preparation in the pharmacopoeia.

→ Assay is done to check the quantity of medicament present in the parenteral preparation.

~~9/2/18~~



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PHARMACEUTICS

QUIZ

1. A rectal suppository is used to treat a fever. This would represent what type of drug delivery?
a) Parenteral and local
b) Parenteral and systemic
c) Enteral and local
d) Enteral and systemic
2. Which one of the following medicines does not rely on topical drug delivery?
a) Nasal spray
b) Anti-dandruff shampoo
c) Insulin pen
d) Nicotine patch
3. From the below options which will be the most widely used form of dosage?
a) Emulsion
b) Solutions
c) Tablets
d) Powders
4. Which of the following terms refers to dosing adjustment?
A: Titration
B: Dosing decrease
C: Maximum therapeutic dose
D: Unit dose change
5. BID in pharmaceutical terms refers to which of the following?
A: Twice a day
B: Twice
C: Every other day
D: Three times a day
6. The formula below is known as which of the following?
A: Young's rule
B: Clark's rule
C: Fried's rule
D: Smith's rule

7. Vaginal suppositories also called as

- (a) Pessaries
- (b) Simple suppositories
- (c) Bougies
- (d) Inserts

8. Which of the following is most commonly used suppository base

- (a) Cocoa butter
- (b) PEG 1000
- (c) PEG + Hexanetriol
- (d) Glycerin

9. Which of the following method is simple & oldest method of preparation of suppositories?

- (a) Hand molding
- (b) Compression molding
- (c) Pour molding
- (d) Paste moulding

10. Of the following oral liquid formulations which would be considered as an oropharyngeal formulation?

- a) Syrup
- b) Elixir
- c) Mouthwash
- d) Linctus

11. Which of the following formulations would not be applicable to ocular administration?

- a) Solution
- b) Liniment
- c) Suspension
- d) Ointment

12. Which of the following dosage forms delivers the API to the GI tract?

- a) Rectal suppositories
- b) Nasal sprays
- c) Vaginal pessaries
- d) Eye drops

13. Given the following are monophasic liquid dosage forms except:

- A. Droughts
- B. Tinctures
- C. Spirits
- D. Enema

14. Posology deals with

- A. Quality of drugs
- B. Dispensing of drugs

- C. Dose of drugs
- D. Stability of drugs

15. Which incompatibility may be corrected by changing the order of mixing?

- A. Delayed
- B. Immediate
- C. Tolerated
- D. Adjusted

16. Crystallization is an example of which incompatibility

- A. Immediate
- B. Delayed
- C. Instantaneous
- D. Adjusted

17. Which is not the part of handling of prescription

- A. Reading
- B. Revision of prescription
- C. Collecting materials
- D. Compounding

18. Signatura is the direction given to

- A. Prescriber
- B. Pharmacist
- C. Patient
- D. Manufacturer

19. Rx is used to denote

- A. Superscription
- B. Inscription
- C. Subscription
- D. Signature

20. Following are the parts of prescription except

- A. Superscription
- B. Inscription
- C. Subscription
- D. Signa

21. Prescription is a

- A. Dietary chart to patient
- B. Diagnosis report to patient
- C. A written order from a registered medical practitioner
- D. Description of patient symptoms

22. The most common criterion used to determine the correct paediatric dose of a drug is

- A. Age
- B. Weight
- C. Gender
- D. Body surface area

23. Which component of the prescription is not always a requirement ?

- A. Inscription
- B. Subscription
- C. Superscription

24. Externally used powders for body cavities are called——.

- A. Detergent
- B. Dusting powder
- C. Talcum powder
- D. Insufflations

25. Which instruction are required on the labels of the powder for dusting powders?

- A. “For internal use only”
- B. “for external use only”
- C. “Shake well before use”
- D. “for insertion”

26. Given the following are biphasic liquid dosage form except

- A. Liniments
- B. Aerosols
- C. Douches
- D. Liniments

27. Given the following are monophasic liquid dosage forms except:

- A. Droughts
- B. Tinctures
- C. Spirits
- D. Enema

28. Following are the disadvantages of liquid dosage form except:

- A. More chance of microbial contamination
- B. Poor stability of medicament
- C. Chance of variation in the doses
- D. Not suitable of hygroscopic substances

29. Which vehicle is very good for throat paints

- A. Propylene glycol
- B. Sorbitol

- C. Glycerol
- D. Poly ethylene glycol

30. Given the following antioxidants are used for aqueous system except:

- A. Sodium thiosulphate
- B. Sodium disulfite
- C. Ascorbic acid
- D. Butylated hydroxyl anisole (BHA)

31. Which is the labeling requirement for suspension?

- A. For external use only
- B. Shake well before use
- C. For internal use only
- D. "Do not use externally"

32. In flocculated suspension the rate of sedimentation:

- A. Slow
- B. High
- C. Absent
- D. Intermediate

33. Given the following are the parts of prescription except:

- A. Date
- B. Subscription
- C. Inscription
- D. Compounding

34. What is used as opacifying agent in face powder?

- A. Zinc oxide
- B. Magnesium oxide
- C. Aluminium oxide
- D. Titanium dioxide

35. Given the following are the liquid dosage forms except:

- A. Eye drops
- B. Nasal drops
- C. Pills
- D. Ear drops

36. Which part of the prescription contains names and quantities of the prescription?

- A. Date
- B. Subscription
- C. Inscription
- D. Superscription



ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ, ಬೆಂಗಳೂರು

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru - 560 041

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE
UNDER GRADUATE PROJECT APPROVAL ORDER

Sub:	Orders for approval of research grants to the UG students of affiliated institutions of RGUHS to carryout research projects for the year 2023-24.reg
Ref:	1. University notification No: RES/UG-RESEARCH/188/2021-22 dated 06-01-2023
	2. Approval of the 180 th Syndicate meeting held on 10-07-2023
Project Code	UG23PHA403
Subject and faculty	Pharmaceutics PHARMACY
Principal Investigator	RANJITHA V
College	R R COLLEGE OF PHARMACY
Name of the Guide/Designation and Dept	Dr. A Geethalakshmi Prof and HOD
Research Project Title	Formulation and Evaluation of Floating In Situ Gel Based Gastro Retentive Drug Delivery of anti-diabetic drug Vildagliptin.
Research Grants Sanctioned	10000
Duration of the Project	Three months from the date of issue of amount through NEFT/RTGS.

One of the main objectives of the University is to promote research activities in the University affiliated colleges. In this regard University had invited applications for financial assistance for conducting the research projects by the UG students of colleges affiliated to RGUHS for the year 2023-24, wherein university received 571 research proposals. The Subject Experts as suggested by the concerned BOS UG chairpersons and the Expert Committee have scrutinized the research proposals and shortlisted them based on the criteria set out by the University. Such of the proposals which have fulfilled the norms, have been recommended by the Expert Committee for sanction of research grants.



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Ref:	1. University notification No: RES/UG-RESEARCH/188/2021-22 dated 06-01-2023 2. Approval of the 180 th Syndicate meeting held on 10-07-2023
Project Code	UG23PHA428
Subject and faculty	Pharmaceutical Chemistry PHARMACY
Principal Investigator	AMISHA
College	R R COLLEGE OF PHARMACY
Name of the Guide/Designation and Dept	Mrs. C Geethapriya Asst Prof
Research Project Title	Synthesis, Insilico studies, Pharmacophore Modelling, HOMO- LUMO Gap analysis for New 1,2,3 Triazole Appended Piperazine with Anti-Oxidant activity.
Research Grants Sanctioned	15000
Duration of the Project	Three months from the date of issue of amount through NEFT/RTGS.

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Ref:	1. University notification No: RES/UG-RESEARCH/188/2021-22 dated 06-01-2023 2. Approval of the 180 th Syndicate meeting held on 10-07-2023
Project Code	UG23PHA424
Subject and faculty	Pharmacology PHARMACY
Principal Investigator	TONHAZ SOBIN HUSSAIN
College	R R COLLEGE OF PHARMACY
Name of the Guide/Designation and Dept	Mr. Vijaya Kumar J Asso Prof
Research Project Title	Evaluation of Faujasiopsis Flexuosa Against Cognitive Impairment in Mice
Research Grants Sanctioned	15000
Duration of the Project	Three months from the date of issue of amount through NEFT/RTGS.

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Ref:	1. University notification No: RES/UG-RESEARCH/188/2021-22 dated 06-01-2023
	2. Approval of the 180 th Syndicate meeting held on 10-07-2023
Project Code	UG23PHA381
Subject and faculty	Pharmaceutical Chemistry PHARMACY
Principal Investigator	USHA. R
College	RR COLLEGE OF PHARMACY
Name of the Guide/Designation and Dept	Dr. S. D. Vachala Professor and HOD
Research Project Title	Ligand based design, synthesis and SAR analysis of some novel 2-substituted-1H-Benzo[d]imidazoles as antineoplastic agents
Research Grants Sanctioned	15000
Duration of the Project	Three months from the date of issue of amount through NEFT/RTGS.

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Ref:	1. University notification No: RES/UG-RESEARCH/188/2021-22 dated 06-01-2023
	2. Approval of the 180 th Syndicate meeting held on 10-07-2023
Project Code	UG23PHA406
Subject and faculty	Pharmacognosy PHARMACY
Principal Investigator	SHARU REJI
College	R R COLLEGE OF PHARMACY
Name of the Guide/Designation and Dept	Mrs. Akila E Asst prof
Research Project Title	Biosynthesis and Design of Ag-Fe Bimetallic Nano particles using a medicinal plant Buchanania lanzan as antimicrobial synergistic combination therapies against clinically relevant pathogens.
Research Grants Sanctioned	15000
Duration of the Project	Three months from the date of issue of amount through NEFT/RTGS.

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INTERNATIONAL CONFERENCE

Approach to Pharmaceutical Insight Through Interdisciplinary Research (APIIR-24)

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In Association With

Association of Pharmaceutical Teachers of India (APTI)

Certificate of Presentation

this is to Certify that

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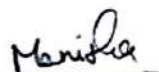
of Department of Pharmaceutical Chemistry, RR College of Pharmacy, Bangalore has Poster Presentation entitled.

APIIR/ABSTR/IC006: Reconnoitring Inhibitors of PIM-1 kinase Triazolopyridazines as Anticancer Agents:

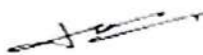
Molecular Modelling Approach

in the Two-Days International Conference on "Approach to Pharmaceutical Insight through Interdisciplinary Research" held at

School of Pharmacy, GHRaisoni University, Saikheda, M.P. on 13th & 14th Nov. 2024.



Dr. Manisha Kawadkar
Associate Professor,
SOP, GHRU, Saikheda, (MP)
Convener



Dr. D. C. Sahu
Professor & Dean,
SOP, GHRU, Saikheda, (MP)
Organizing Chair



Dr. Milind J. Umekar
President,
Association of Pharmaceutical
Teachers of India (APTI)



Dr. Meena Rajesh
Vice Chancellor,
GHRU, Saikheda, (MP),
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of Department of Chemistry, RR College of Pharmacy, Bangalore has Poster Presentation entitled.

APIIR/ABSTR/ICo17: Targeting Viral Proteins with Pyrimidine Derivatives: An Insilico Studies of

Antiviral Agents

in the Two-Days International Conference on "Approach to Pharmaceutical Insight through Interdisciplinary Research" held at

School of Pharmacy, GHRaisoni University, Saikheda, M.P. on 13th & 14th Nov, 2024.



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Dr. Milind J. Umekar
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Dr. Meena Rajesh
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INTERNAL QUALITY ASSURANCE CELL (IQAC)

BIOPHARMACEUTICS AND PHARMACOKINETICS QUESTION BANK

UNIT I – BIOPHARMACEUTICS: ABSORPTION

1. Define Absorption. Discuss in detail the various biological factors affecting drug absorption.
2. Discuss in detail the various physico-chemical factors affecting drug absorption.
3. Discuss in detail the various physiological factors affecting drug absorption.
4. Discuss in detail the various pharmaceutical factors affecting drug absorption.
5. Explain the various mechanisms of drug absorption.
6. Define drug distribution. Describe the factors affecting distribution.
7. Write in detail about protein binding and its significance.
8. Define biotransformation. Explain with examples phase I and phase II reactions.
9. What is clearance? Give the formula for the same. Explain organ clearance and hepatic extraction ratio.
10. Explain the process of renal elimination.
11. How do you calculate the pharmacokinetic parameters for a drug undergoing metabolism from the urine data? Give the relevant graphs.
12. How do you calculate the pharmacokinetic parameters for a drug (no metabolism) from the urine data? Give the relevant graphs.
13. Draw a typical plasma concentration time profile curve following oral, IV bolus and IV infusion and explain the pharmacokinetic parameters that can be determined from the same.
14. Compare and contrast passive diffusion versus active transport. Add a note on facilitated transport.
15. What do you understand by pH-partition theory? Give its importance and its limitations.

DISTRIBUTION

15. Write about the significance of protein binding.
16. Explain the kinetics of protein binding.
17. Explain about binding of drugs to HAS (Human Serum Albumin).
18. Write about plasma protein binding of drugs.
19. Define volume of administration and give its significance.
20. Define volume of administration and how do you determine V_d ?
21. How is drug distributed to CNS through blood brain barrier ?
22. Explain drug distribution to foetus through placental barrier.
23. Explain intra cellular and extra cellular binding of drugs.

ELIMINATION

24. Explain renal clearance of drugs.
25. How do you determine renal clearance of drugs ?
26. Explain hepatic extraction ratio and its importance.
27. Explain various non-renal routes of excretion.
28. Explain hepatic clearance.
29. Explain glucuronic acid conjugation.
30. Explain phase I reactions.
31. What is biotransformation and explain its importance.
32. Explain the hepatic metabolism of drugs.
33. Explain the pre systemic metabolism of drugs.
34. List out the various factors affecting biotransformation and discuss any two.
35. List out the various factors affecting excretion and discuss any two.

2 marks

1. Write briefly about Active transport
2. Draw the Structure of Cell membrane
3. What is Facilitated diffusion?
4. What is Pinocytosis and phagocytosis?
5. What is Endocytosis?
6. Write modified Noyes Whitney's equation.
7. What is polymorphism.
8. Name rate limiting steps in drug absorption.
9. What is the effect of food on absorption of drugs?
10. How particle sizes affect the drug absorption?
11. How do solvates and hydrates affect drug absorption?
12. Give two examples of drugs which are unstable in the GIT.
13. List out the methods to study absorption of drugs.
14. How drugs are classified according to BCS?
15. List the orally administered dosage form in order of their increasing absorption.
16. Define drug distribution.
17. Define protein binding.
18. What are distribution characteristics of protein bound drug?
19. Mention the significance of protein binding.
20. Mention the significance of tissue binding.
21. Define biotransformation.
22. What are xenobiotic?
23. What is clearance? Give the formula for same
24. What is enterohepatic cycle?
25. What do you understand by inhibition and induction?
27. Name the various barriers for drug distribution.
28. List out the non renal routes of drug excretion.
29. Hepatic clearance. Mention its significance.

UNIT II –PHARMACOKINETICS, ONE COMPARTMENT MODEL, TWO COMPARTMENT MODEL

1. What do you understand by pharmacokinetic model? Classify the pharmacokinetic models, give their salient features, advantages and disadvantages.
2. Discuss in detail one-compartment open model for a drug administered as IV Bolus. Give the schematic representation, graphs and equations for the same.
3. Discuss in detail one-compartment open model for a drug administered as IV infusion. Give the schematic representation, graphs and equations for the same
4. Discuss in detail two-compartment open model for a drug administered as IV Bolus. Give the schematic representation, graphs and equations for the same.
5. What is a compartment? Classify the compartment models. Give the schematic representation of the same.

5 MARKS

1. Write a note on Catenary and mammillary modeling.
2. Write the importance of Compartment modeling in pharmacokinetic study.
3. With a neat labeled diagram explain the drug levels in blood after oral administration.
4. Explain various pharmacokinetic parameters after oral administration of drug.
5. Write the applications of pharmacokinetic models.
6. Explain how steady state level of the drug is achieved through I.V infusion.
7. Give schematic representation of two and three compartment models with brief explanation.
8. Explain the assumptions of one-compartment open model
9. Write about the advantages and disadvantages of compartment modeling.
10. Compare blood level curves between I.V and oral routes with a graph.
11. Give the monoexponential and biexponential equations for drugs administered as IV bolus and explain the terms.
12. How do you determine KE using rate of excretion method from urine data.
13. How do you determine KE using sigma minus method from urine data.

2 marks

1. Define pharmacokinetics.
2. In compartment modelling why does excretion takes place from central compartment
3. What are the limitations of one compartment model
4. Define elimination rate constant?
5. Describe the influence of K_e on C_{max} , T_{max} and AUC.
6. Mention the methods for calculating of AUC.
7. Define biological half life.
8. Enumerate the applications of pharmacokinetics.
9. What is first order and second order reaction?
10. What is Zero order reaction?
11. Write equation for zero and first order half life.
12. What do mean by therapeutic index?
13. Give an example for Mono exponential equation.
14. Give an example for Bi exponential equation.

15. Draw the blood level profiles for oral and intravenous route of administration.
16. Enlist different pharmacokinetic parameters.
17. Define C_{max} and T_{max}.
18. Classify Pharmacokinetic models.
19. What is multi compartment model?
20. Give the schematic representation of one compartment open model-oral.
21. Give the schematic representation of one compartment open model-IV.

BIO-AVAILABILITY AND BIOEQUIVALENCE

1. Define bio-availability and bio-equivalence.
2. Differentiate between absolute and relative bioavailability.
3. Give the significance of bio-equivalence.
4. List out the methods to calculate AUC.
5. Give an example for Latin square cross over design for the conduct of bioavailability study.
6. Name any four methods for enhancing bio-availability of drugs.
7. Define therapeutic equivalence and chemical equivalence.
8. Give the equation to calculate bio-availability from urine data?
9. Name the methods to calculate K_e from urine data.

NON-COMPARTMENTAL ANALYSIS

1. Explain statistical moment's theory.
2. Give the formula for AUMC and MRT.
3. What are the advantages of physiological model?
4. What is the difference between AUC and AUMC?
5. Define MRT and give its equation.
6. Give schematic representation for Physiological –Pharmacokinetic

NON LINEAR PHARMACOKINETICS

1. What is the difference between linear and non-linear PK?
2. List out the reasons for non-linearity in PK studies.
3. Write the tests to determine non-linearity.
4. Give Michaelis-Menton equation. Explain the terms.
5. What is K_m and V_{max}?