

The Answer-book is bar coded. Identity of the student in any form should not be revealed in the answer-book/supplementary sheet.

SUPERVISOR'S
SIGNATURE
WITH DATE

D. Hsonauts
29/01/25



stick here

DATE: 29/01/25

PROGRAMME: Bpharm + mba

TRIMESTER/SEMESTER: VI

SPECIALISATION:

DIVISION: A

COURSE/SUBJECT: Biopharmaceutics & pharmacokinetics

MAIN ANSWER BOOK: + SUPPLEMENTARY SHEET/S: = (TOTAL TO BE FILLED BY STUDENT)

QUESTION NOS.	1	2	3	4	5	6	7	8	9	10	11	12	TOTAL MARKS OBTAINED	MAXIMUM MARKS
(MARKS OBTAINED) (TO BE FILLED IN BY FIRST EXAMINER)														

SIGNATURE OF THE FIRST EXAMINER

QUESTION NOS.	1	2	3	4	5	6	7	8	9	10	11	12	TOTAL MARKS OBTAINED	MAXIMUM MARKS
(MARKS OBTAINED) (TO BE FILLED IN BY SECOND EXAMINER / MODERATOR)														

SIGNATURE OF THE
SECOND EXAMINER / MODERATOR

QUESTION NOS.	1	2	3	4	5	6	7	8	9	10	11	12	TOTAL MARKS OBTAINED	MAXIMUM MARKS
(MARKS OBTAINED) (TO BE FILLED IN BY THIRD EXAMINER)														

SIGNATURE OF THE
THIRD EXAMINER

INSTRUCTIONS TO BE STRICTLY FOLLOWED BY CANDIDATES

- This answer-book contains thirty two pages. Check whether the relevant answer-book provided contains thirty two pages and whether the pages are properly numbered.
- Candidates should occupy their correct seats as per the seating plan displayed and write appropriate details in the space provided for the purpose on the answer-book.
- Candidates must produce their photo identity card provided by the University for verification to the room supervisor during the examination. Candidates will not be permitted to appear for the examination without the identity card.

4. As per the rules, Candidates, who are not in their seats by the time notified, will not be permitted to appear for the examination.
5. Candidates should ensure that all answer-books including supplementary sheets provided to them bear the signature of the room supervisor and date of examination without which the answer-book will not be examined.
6. Tie all supplementary sheets to the main answer-book relating to the same paper and enter on the first page of the answer-book, the total number of supplementary sheets tied together.
7. Begin answer to each question on a new page. For each answer, write the corresponding question number in the left hand side margin, provided for the same.
8. **Do not write anything in the right hand side margin provided for marks to be assigned by the examiner.**
9. Candidates will not be permitted to leave the examination hall until half an hour after the question papers are distributed. Apart from certain specific conditions such as medical emergency, natural calamity etc., candidates will not be allowed to leave the examination hall during the examination until they submit their answer-book to the room supervisor.
10. Every Candidate present must sign against his / her Student number on the attendance sheet provided by the room supervisor.
11. **Candidates are forbidden to (i) bring any book, notes, scribbling paper, pages, mobile phones, laptop or any other similar devices/things. Any such material found in possession of the Candidate will be confiscated, (ii) smoke in the examination hall, (iii) bring eatables / drinks in the examination hall, (iv) speak or communicate in any manner with any other candidate, while the examination is in progress, and (v) take with them any answer-book, written or blank, while leaving the examination hall. Such acts amount to adoption of unfair means by the candidate/s concerned and strict action will be taken against them. The supervisors/authorised person are authorised to frisk the Candidates.**
12. Candidates suspected to be guilty of any of the aforesaid acts will be allowed to write examination only after giving an undertaking in writing that the decision of the University in respect of the reported act of unfair means will be binding on them.
13. Any method to bribe the examiner/s by attaching currency notes or letters or making appeal inside the answer-book is strictly prohibited and will result in serious action taken by the University.
14. **Candidates should write legibly and with blue / black pen. Answers written in illegible handwriting or with pencil may not be evaluated.**
15. Candidates should write on both sides of a page. Rough work, when necessary, should be done only in the answer-book by specifically marking the page as Rough Work.
16. **Candidates should not write their name, Roll No. Student No. etc. anywhere in the answer-book and reveal their identity in any form in the answer written by them. Writing these details, or putting signature is revelation of identity. Use of religious invocation or any writing that is not relevant anywhere in the answer-book will be treated as attempt to reveal one's identity.**
17. While underlining of answer for focusing attention is permitted, use of varied inks for illustration and figures must be avoided. DO NOT use any symbol like encircling the question or using arrows for 'P.T.O.' These will be considered as attempts to readily identify the specific answer-book.
18. The answer-books will be scrutinised before they are sent to examiners. If the University authorities are convinced that any candidate has attempted to reveal his/her identity by any means, the answer-book/s may NOT be sent to the examiner for evaluation and the Candidate's case will be dealt with as per Examination Rules of the University.
19. **Candidates should neither tear any sheet/s from the answer-book provided nor shall attach additional sheets to them, except the Supplementary sheets if needed, the details of which should be provided as per point No. 6.**
20. Severe penalty would be imposed on the Candidates who are found to be involved in the adoption of unfair means in the examinations.
21. The answer-book/supplementary sheets whether written or blank should be returned back to the room supervisor. Smuggling / Carrying the Answer book / Supplementary sheet in / out of the examination hall will amount to adoption of unfair means.
22. Candidates should not write anything on the question-paper.
23. Exchange of writing material, stencils, mathematical instruments, question-paper, etc., is strictly prohibited.
24. If candidates want anything, they should approach the room supervisor without disturbing other candidates. However, they should not leave the examination hall for any purpose.
25. Candidates will not be allowed to leave the examination hall during the last ten minutes. They must tie their supplementary sheets if any to the main answer-book in time and hand over their answer-books to the room supervisor. They should not leave their seats until answer-books from all candidates are collected by the room supervisor.
26. **A candidate who disobeys any instructions issued by the Senior / Room Supervisor or who is guilty of rude or disobedient behaviour is liable for disciplinary action to be taken against him / her by the University.**

"IT IS PRESUMED THAT THE CANDIDATE HAS READ ALL THE ABOVE INSTRUCTIONS.

Question
Nos.Objective Type

Ans 1:-

- Key proteins responsible in drug binding :-
 e.g. aspirin
- Human serum albumin → Acidic drugs bind to this protein
 - Cytocarneins → basic drugs bind more.
 e.g. propantheline
 - Lipoproteins
 non ionic lipophilic drugs have more affinity to bind to this.
 → warfarin.

Ans 2:- Vitamin B is absorbed by carrier transport mechanism, which is intrinsic factor. There are limited no. of carriers, so, limited no. of drug can be absorbed.

Administering large dose will fill all carrier proteins & rest of drug will be excreted without getting absorbed.

Ans 3:- Diff. barriers that affect drug distribution process:-

- Placental Barrier:- Protects foetus from drugs, only highly lipophilic drugs pass.
- Blood Brain Barrier:- Prevent drug from affecting Brain drugs following Lipinski rules only pass.

Question
No.

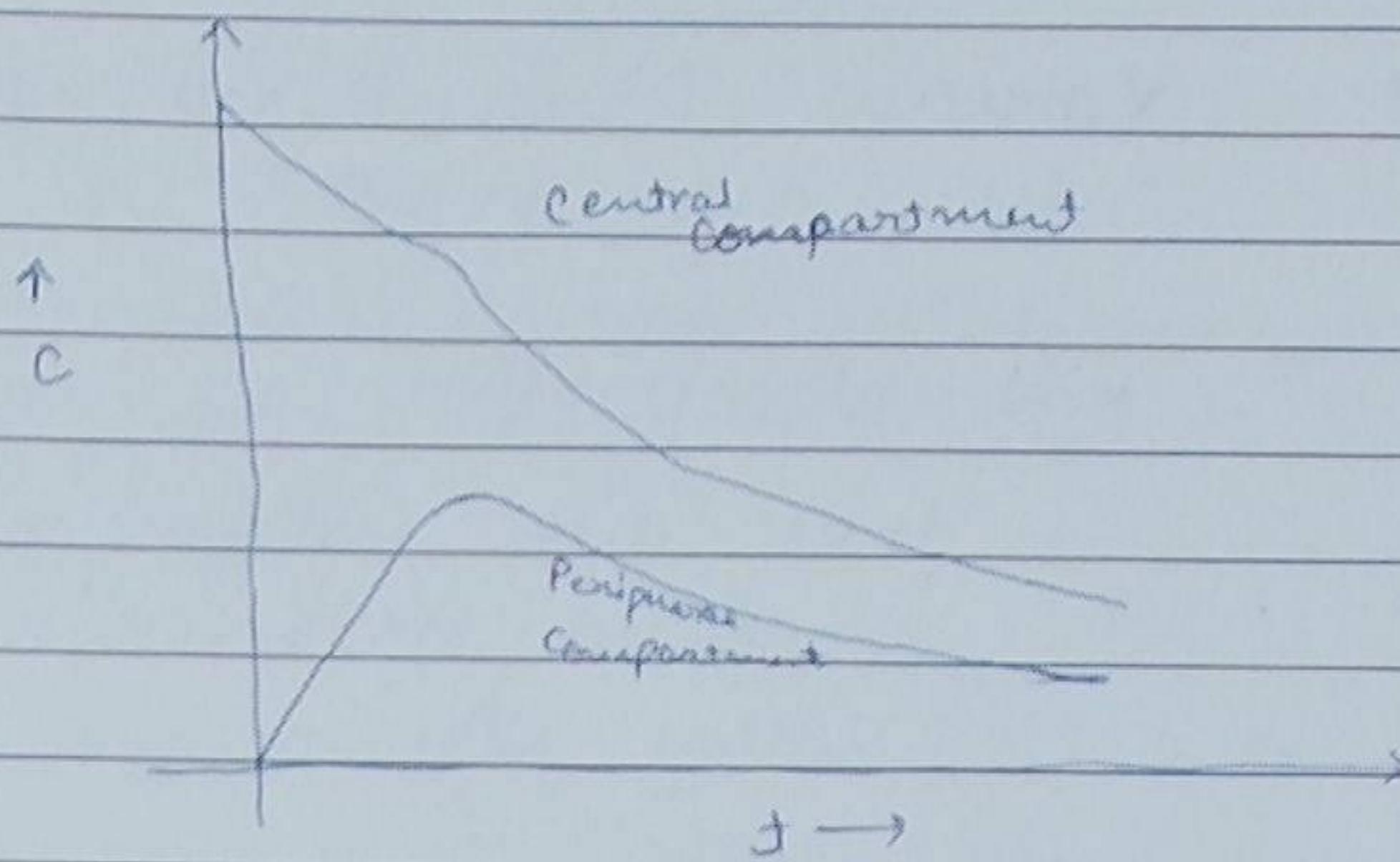
Ans 4:- rate of elimination is greater than rate of absorption. So, the slope of residual line is declining.

Ans 5:- measurement of metabolites in urine will not give correct measure of bioavailability because elimination of drug may occur from tears, sweat, saliva, etc.

Ans 6:-

Question
Nos.

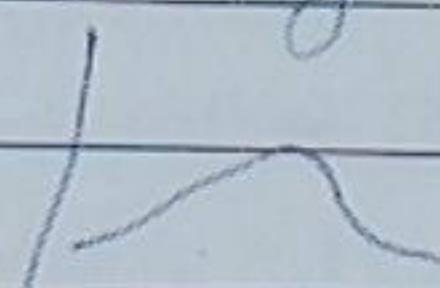
Ans:-



- first ^{when} drug is administered it is present in central compartment.
- Due to Rapid Distribution in peripheral compartments as well as elimination Drug concⁿ will decrease rapidly.
- when central & peripheral ^{compartment} have achieved similar conc. of drug by distribution, drug level of central compartment slowly decreases as shown in above graph ↴

Peripheral comp.: -

- first drug is absorbed, as graph shows increase in concⁿ initially
- then it is decreasing.



Question
No.

Ans3:- Various Drug Binding sites on HSA :-

→ α -1-glycoprotein

drug like warfarin, aspirin
bind here.

→ α -2 binding site

→

Ans4:- Non - renal routes of drug excretion :-

→ Via saliva

→ Via sweat/ perspiration

→ Via tears

→ Via oil glands/salacious glands

Ans5:- Rotten aftermath of medicaments in patient undergoing drug therapy can be because of drug being excreted by salivary secretions.

Long Answer

Ans 1:-

(a) physicochemical factors influencing the drug absorption in GIT:-

- Solubility.
- Dissolution.
- Disintegration.
- Ionisation.
- Particle size.
- pH
- Lipophilicity → ↑_{ss} permeation rate.
- Hydrophilicity → ↑_{ss} dissolution rate.

⇒ Log P

patient related factors:-

- age
- gastric motility
- Disease conditions.

(b) (i) Solubility - Drug should be highly soluble, it will only get absorbed if it is in solution form. Also, it should be lipophilic to cross membrane & go into blood flow.

Log P value should be close to 5, for a drug to be lipophilic.

Question No.

(ii) Ionisation:- Drug should be ionisable, it makes it more soluble. It is present in both ionised & un-ionised form in solution. Only un-ionised form of drug is absorbed.

(c) Two formulation strategies:-

→ nanomisation:- It involves reduction of drug particle size & thus increases absorption.

→ Supercritical fluid extraction:-
In this method drug is formulated in its ~~for~~ critical temp., at critical temp. it is highly compressible. Thus, it can be formulated as very small particles.

→ Formulating with cyclodextrins.

Question
No.

Ans 2:- Concept of Compartment models:-

→ If our body is divided into diff.

Compartment :-

→ Central compartment :- compartment with high blood perfusion.

→ peripheral compartments :- compartments with low blood perfusion.

e.g. of central comp. :- Heart, lungs, Liver, Kidneys, etc.

e.g. of peripheral compartments :-

fatty/Adipose tissue, skin, etc.

→ By dividing Body in diff. compartment, drug absorption, distribution, metabolism, elimination properties are studied.

Applications:-

→ Help to administer/calculate write dose for patient.

→ To achieve steady state concentration in IV infusion.

→ Administration of loading dose in drugs with longer half life.

Question
No.

(b) characteristics of drug exhibiting non-linear pharmacokinetics:-

- ⇒ Some drugs show non-linear pharmacokinetics, ~~more~~ This may occur because :-
 - absorption due to co-factors (ex → B_{12} absorbed by intrinsic factor)
 - due to some disease condition.

Non-linear elimination:-

- This may occur in some cases where metabolites also degrade drug.

Short Answers

Ques 2:- Distribution of drug is not uniform throughout the body. factors that influence drug distribution are :-

⇒ Lipophilicity :- highly lipophilic drugs have high permeation & are distributed highly.

They can even cross BBB & placental Barrier.

e.g.;- Aspirin.

⇒ They have very good tissue perfusion

⇒ Protein Binding:- Drugs having high affinity towards HSA, Glycoprotein & Apoproteins, get bound to these & will distribute less.

⇒ Drug with high molecular size do not distribute frequently & have less Vd

Drug distribution is not Uniform throughout because there may be some tissue which have ~~low~~ high ~~ability~~ permeation & some which may not have enough affinity. Usually, it also depends on Blood perfusion, tissues like adipose tissue & skin have less blood perfusion & thus also have less drug distributed to them.

Question
No.

Ans 3:-

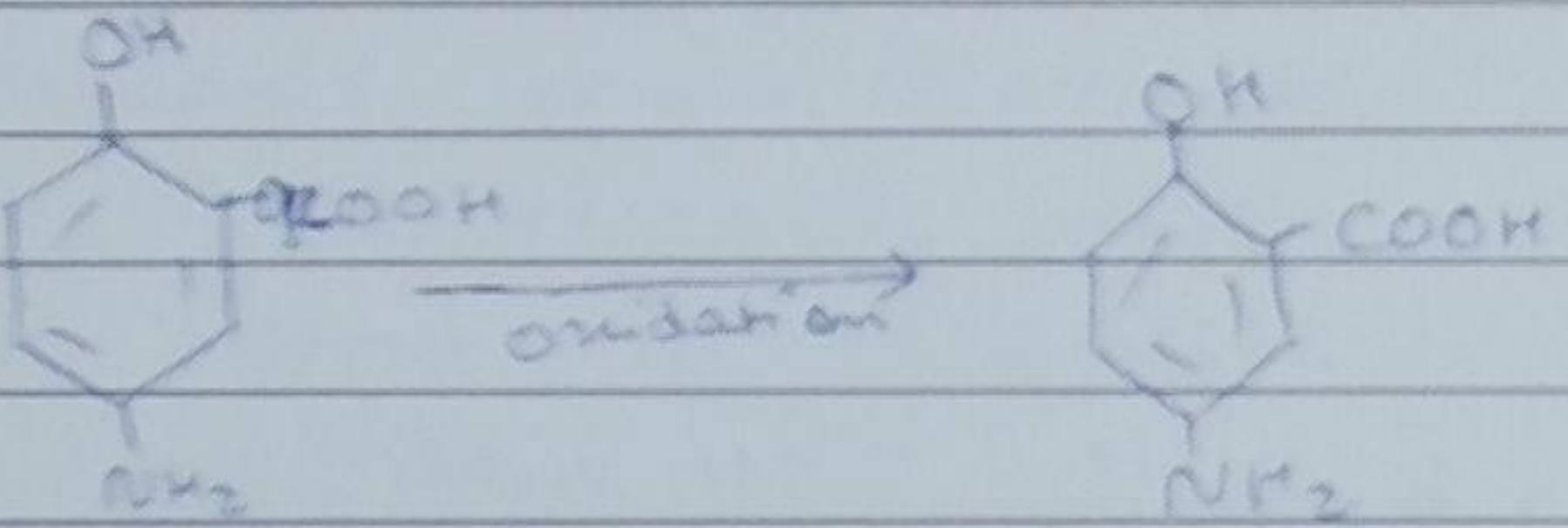
→ Phase I metabolic pathway occurs in hepatic microsomes.

→ These metabolic pathways usually involve oxidation & reduction of drugs & other molecules.

→ These metabolic reactions have several CYP enzymes as catalyst.

e.g.: - Cyp 3A4, Cyp 340, etc

e.g. →



Question
No.

Ans:- Clearance is the time taken by the tissue/organ to completely eliminate the drug.

$$Cl_T = B \left(\frac{C_{in} - C_{out}}{C_{in}} \right)$$

$B \rightarrow$ Blood flow

$C_{in} \rightarrow$ Concentration rate in

$C_{out} \rightarrow$ rate out.

Organ clearance :- Time taken by drug to completely eliminated from the organ

Total clearance is sum of all organ clearance

$$Cl_T = Cl_g + Cl_k + Cl_{liver} + \dots \text{etc}$$

\downarrow \downarrow
Liver kidney

Hepatic extraction ratio :-

Amount of drug cleared by liver

Question
No.

Ans 9:-

Drug	Dose (mg/kg)	Dose(mg)	AUC
I.V	1.2	$\times 50 \rightarrow$ 60mg	430
Oral soln	4.0	$\times 50 \rightarrow$ 200mg	822
capsule	4.0	$\times 50 \rightarrow$ 200mg	736
S.R. Tab	6.0	$\times 50 \rightarrow$ 300mg	1040

a) ~~$\frac{200 \times 1040}{736 \times 400} \times 2$~~

absolute Bioavailability

$$\text{Capsule} = \frac{\text{Bio capsule}}{\text{Bio of I.V.}}$$

$$= \frac{736 \times 1040}{60 \times 400} \times 2$$

b) relative BA of cap. against oral soln

$$= \frac{\text{BA Cap}}{\text{BA Oral soln}} \times 100$$

relative BA of S.R. against oral soln

$$= \frac{\text{BA of S.R.}}{\text{BA of oral soln}} \times 100$$

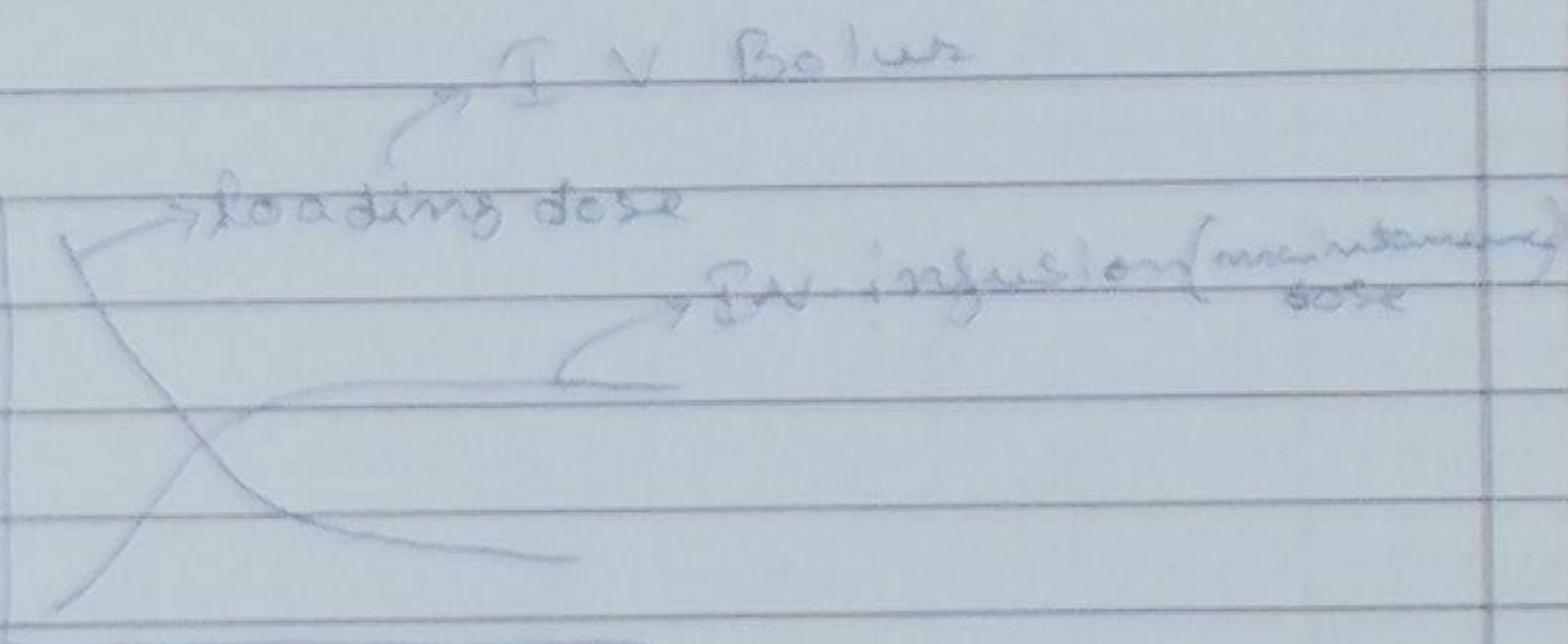
c) oral capsule shows better bioavailability.

Question
No.

6 → Loading Dose :- To maintain steady state concentration in therapeutic range immediately, loading dose is given, as I.V. Bolus

Maintenance Dose :-

This is the dose equivalent to elimination rate of drug.



Loading dose is given as per the therapeutic range.

Maintenance dose is calculated by knowing elimination rate of drug. Maintenance dose is equal to the drug elimination rate.

Question
Nos.

8. (i) Using healthy volunteers:-

Pros :-

→ Normal Absorption, distribution, metabolism & elimination properties can be studied.

Cons :-

→ In this action of drug on actual disease can not be studied.

Using patients:-

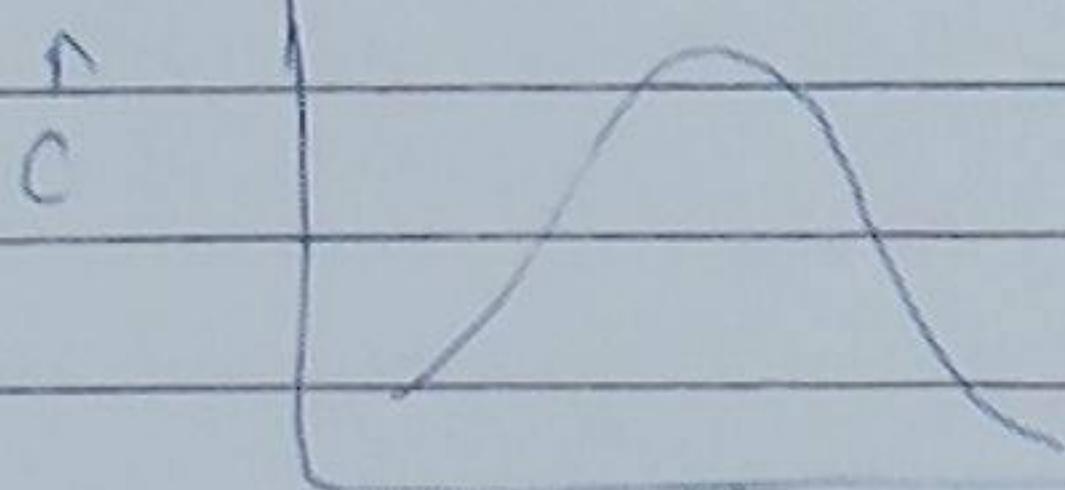
Pros :-

→ actual effect of drug on patient health can be studied.

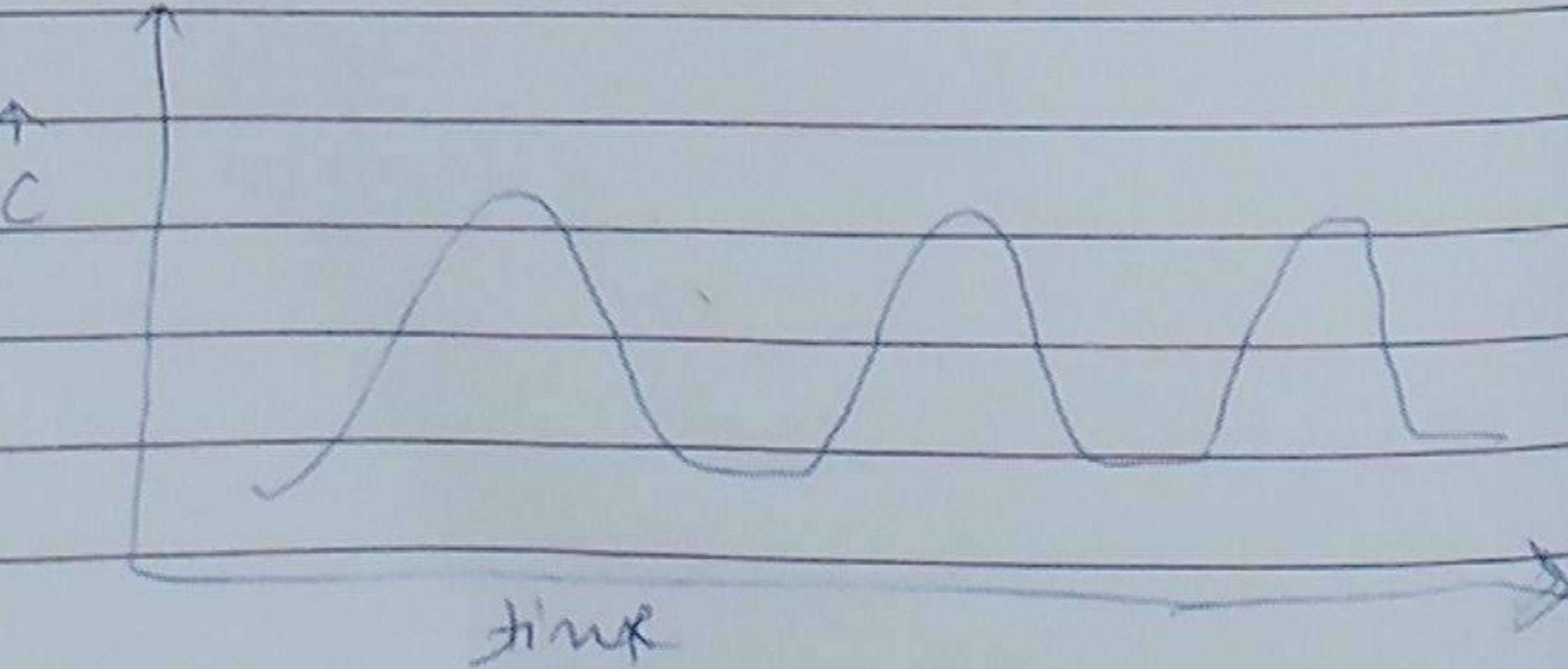
Cons :-

→

Single dose



Multiple dose :-



Question
Nos.

Question
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Question
Nos.

Question
Nos.

Question
Nos.

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