GPAT 2027-28

PHARMACOLOGY

CLASS- 14

TIME- 8 : 30 P.M

PHARMACOTHERAPY, CLINICAL PHARMACOLOGY & DRUG DEVELOPMENT

UPDATED QUESTIONS *TILL GPAT 2026*

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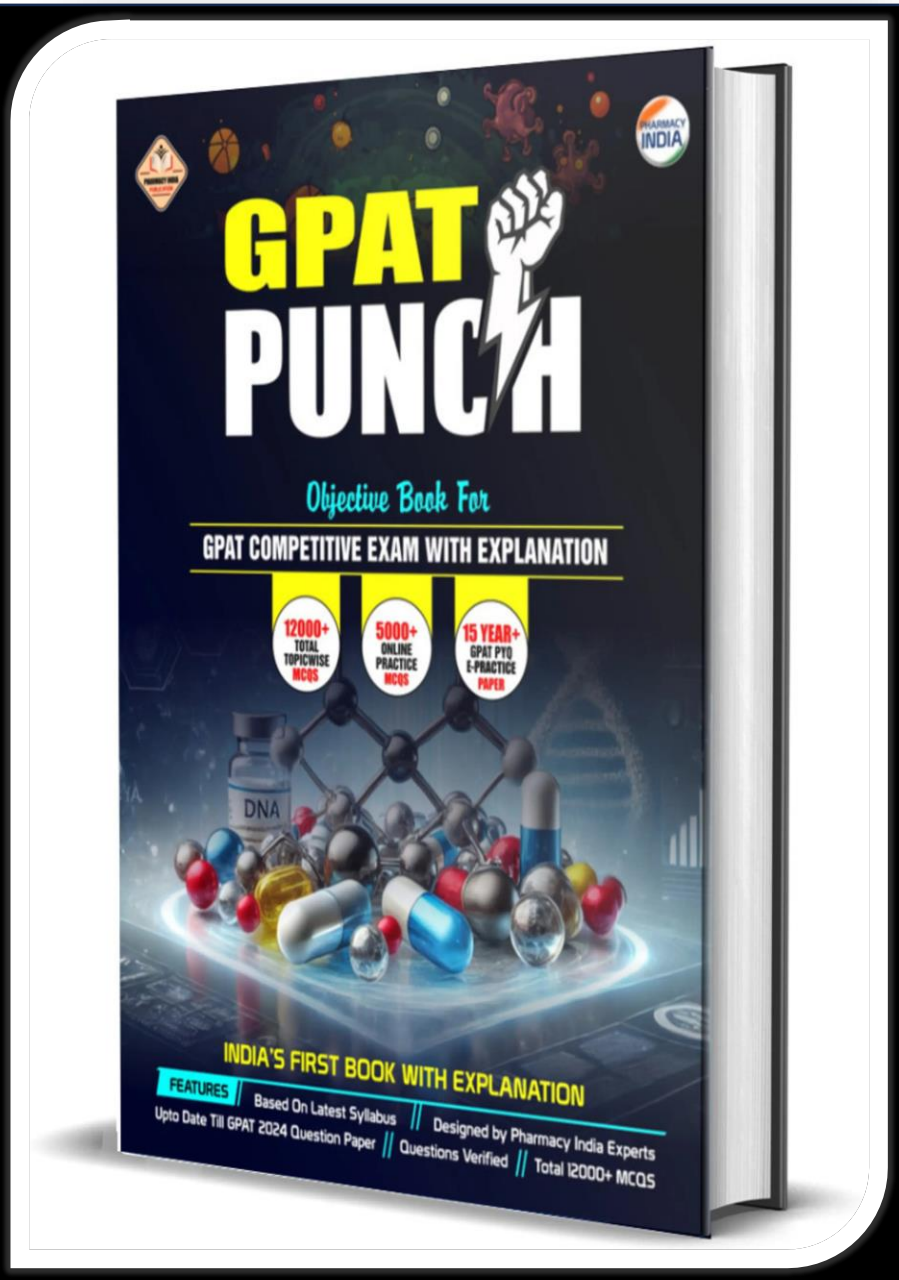

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के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

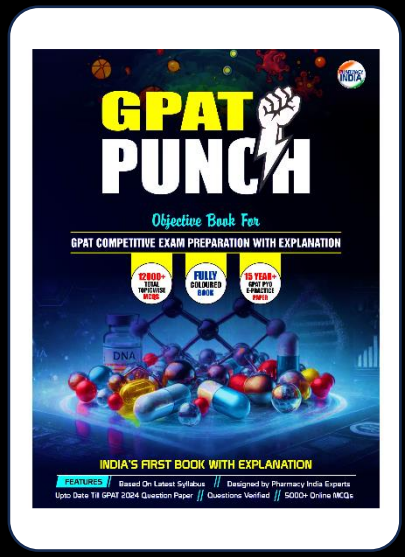
01. **When is a New Drug Application made? [GPAT-2023 SHIFT-I]**

(a) Once animal studies are done and the drug is declared safe in animals

(b) Once animal studies are done and the drug is declared safe and effective in animal studies

(c) After Phase III clinical trials

(d) After Phase IV clinical trials



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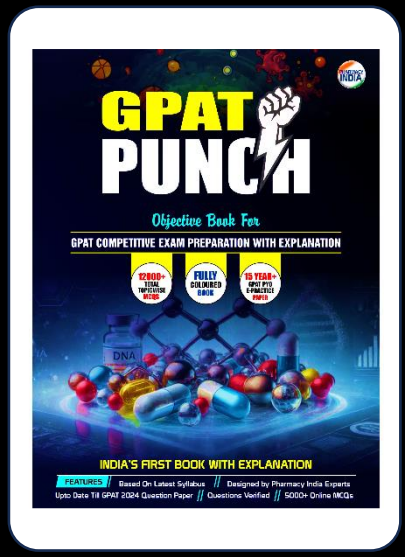


NEW DRUG APPLICATION (NDA)

NDA is filed after successful completion of **Phase III** clinical trials.
It is submitted to the **regulatory authority** for review and **market approval.**

PRECLINICAL

Laboratory & animal studies

PHASE I

20–100 Healthy Volunteers
Safety & dosage

PHASE II

100–300 Patients
Efficacy & side effects

PHASE III

300–3000+ Patients
Therapeutic confirmation

NDA

SUBMITTED TO REGULATORY AUTHORITY

Review of quality, safety & efficacy data

AFTER PHASE III

NDA is filed only after successful completion of Phase III trials.

THERAPEUTIC CONFIRMATION COMPLETED

Efficacy and safety are well established.

SUBMITTED FOR EVALUATION

Comprehensive data package submitted to the regulatory authority for review.

GOAL: MARKET APPROVAL

To ensure the drug is safe, effective and of high quality for patient use.

APPROVAL

Market Approval & Patient Access

NDA = THE FINAL STEP TOWARDS MAKING A SAFE, EFFECTIVE & HIGH-QUALITY DRUG AVAILABLE TO PATIENTS.

02. **Match the following phases of clinical trial with their significance: [GPAT-2022]**

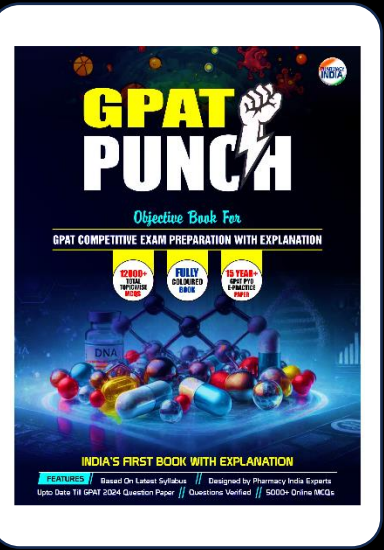
1. Phase I — P. Post-marketing surveillance
2. Phase 0 — Q. Microdosing
3. Phase III — R. First in human dose
4. Phase IV — S. Multicentric trials

(a) 1-R, 2-Q, 3-P, 4-S

(b) 1-R, 2-Q, 3-S, 4-P

(c) 1-Q, 2-S, 3-P, 4-R

(d) 1-S, 2-P, 3-Q, 4-R



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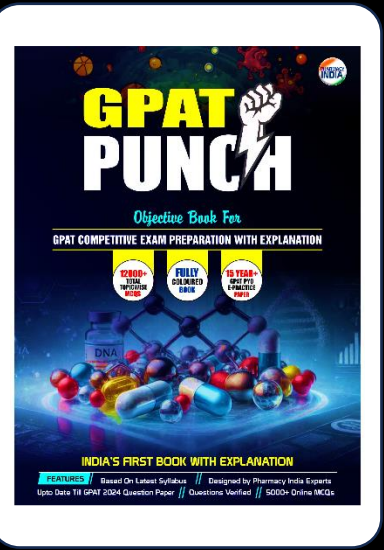


CLINICAL TRIAL PHASES

PHASE	SIGNIFICANCE
PHASE I • 20–100 healthy volunteers • Safety, tolerability, dose range	**FIRST-IN-HUMAN DOSE** Evaluates initial safety and helps find the safe dose range.
PHASE 0 • 10–15 healthy volunteers • Sub-therapeutic (micro) dose	**MICRODOSING** Assesses early human PK/PD with minimal risk.
PHASE III • Hundreds to thousands • Confirms efficacy & monitors adverse effects	**MULTICENTRIC TRIALS** Large, multicenter studies confirm efficacy and safety across populations.
PHASE IV • After regulatory approval • Real-world patient population	**POST-MARKETING SURVEILLANCE** Monitors long-term safety, rare adverse events, and real-world effectiveness.

WHY CLINICAL TRIALS MATTER

- Ensure Safety
- Prove Efficacy
- Support Regulatory Approval
- Improve Patient Outcomes
- Advance Science & Better Therapies

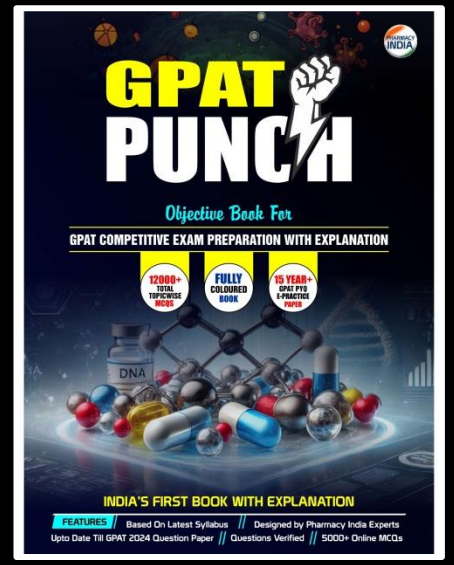
03. **The objective of Abbreviated New Drug Application is to: [GPAT-2022]**

(a) Get approval to conduct clinical trials

(b) Get market approval of new chemical entities

(c) Get market approval of generics

(d) Get approval for animal studies of new chemical entities



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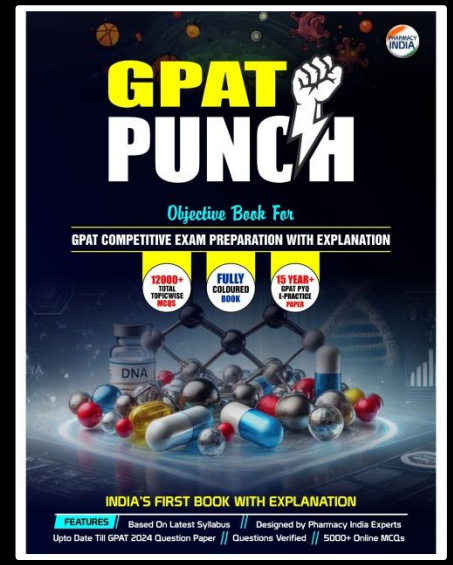


ABBREVIATED NEW DRUG APPLICATION (ANDA)

ANDA is used to obtain market approval of generic drugs.

GENERIC DRUG

ANDA SUBMISSION

ANDA

- Chemistry, Manufacturing and Controls (CMC)
- Bioequivalence (BE) Studies
- Labeling
- Administrative Information

FDA REVIEW FOCUS

QUALITY
Ensure same quality as the reference drug

BIOEQUIVALENCE
Show similar rate and extent of absorption

SAFETY
Rely on proven safety of the reference drug

LABELING
Same labeling as the reference listed drug

APPROVAL & MARKET

ACCESS TO LOWER-COST GENERICS

★ KEY POINTS ★

- For generic drug approval
- Focus on bioequivalence and quality
- No need to repeat full new-drug efficacy development
- Supports access to lower-cost generics for patients

ANDA = Abbreviated New Drug Application | **Goal:** Prove sameness in quality + bioequivalence, **not** new clinical efficacy.

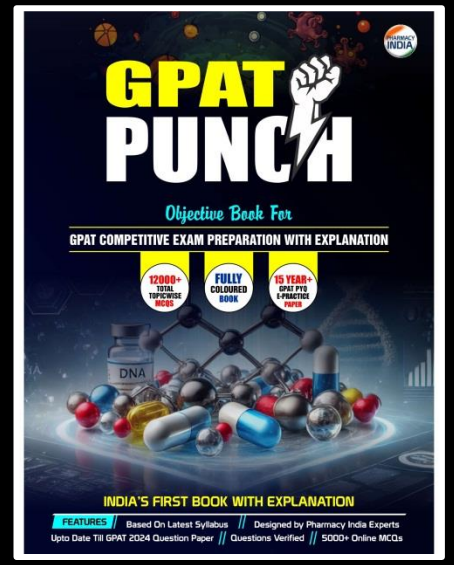
04. **Monitoring the safety of a new drug under actual conditions of use in a large number of patients is classified as which phase of clinical trial? [GPAT-2021]**

(a) Phase III

(b) Phase II

(c) Phase IV

(d) Phase I



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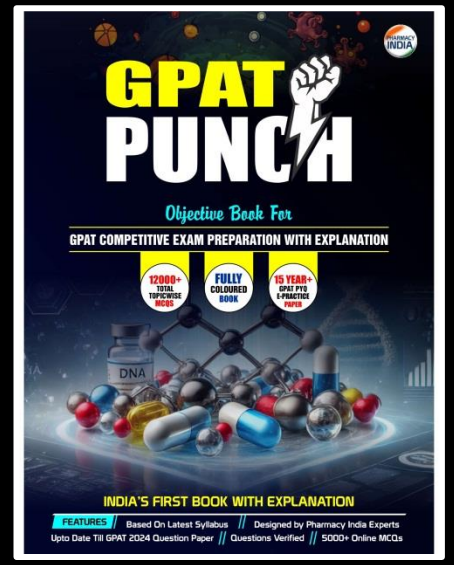


PHASE IV SAFETY MONITORING

Monitoring the **safety** of a **new drug** in a **large number of patients** under **actual** conditions of **use** is **Phase IV** clinical trial, also called **post-marketing surveillance**.

REAL-WORLD USE
Drug is used in everyday clinical practice.

LARGE PATIENT POPULATION
Includes diverse age, sex, and co-morbidities.

DETECTS RARE AND DELAYED ADVERSE EFFECTS
Identifies long-term and uncommon risks.

POST-MARKETING SURVEILLANCE
Continuous monitoring after the drug is approved.

SAFE TODAY, SAFER TOMORROW

CONTINUOUS SAFETY MONITORING

- Collects data from reports, registries, electronic records, and study studies.
- Identifies new safety signals.
- Ensures ongoing patient safety.
- Updates labeling and guides safe use.

GOAL: Identify risks early → Protect patients in real world → Improve drug safety profile → Better outcomes, stronger trust

05. Identify the phase of clinical trial having the following features: [GPAT-2020]

[P] Trial is conducted on about 3000 patients

[Q] Purpose of trial is therapeutic confirmation

[R] Safety and tolerability are evaluated on wider scale

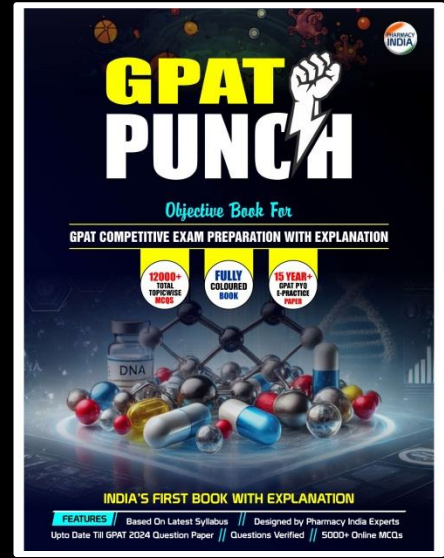
[S] Completion of trial is followed by New Drug Application

(a) Phase III

(b) Phase I

(c) Phase IV

(d) Phase II



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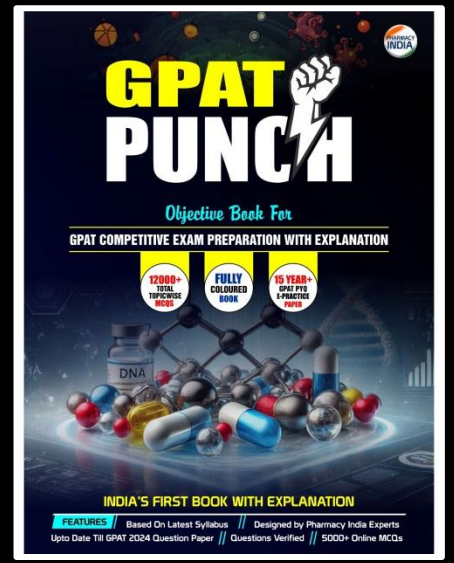


PHASE III TRIAL FEATURES

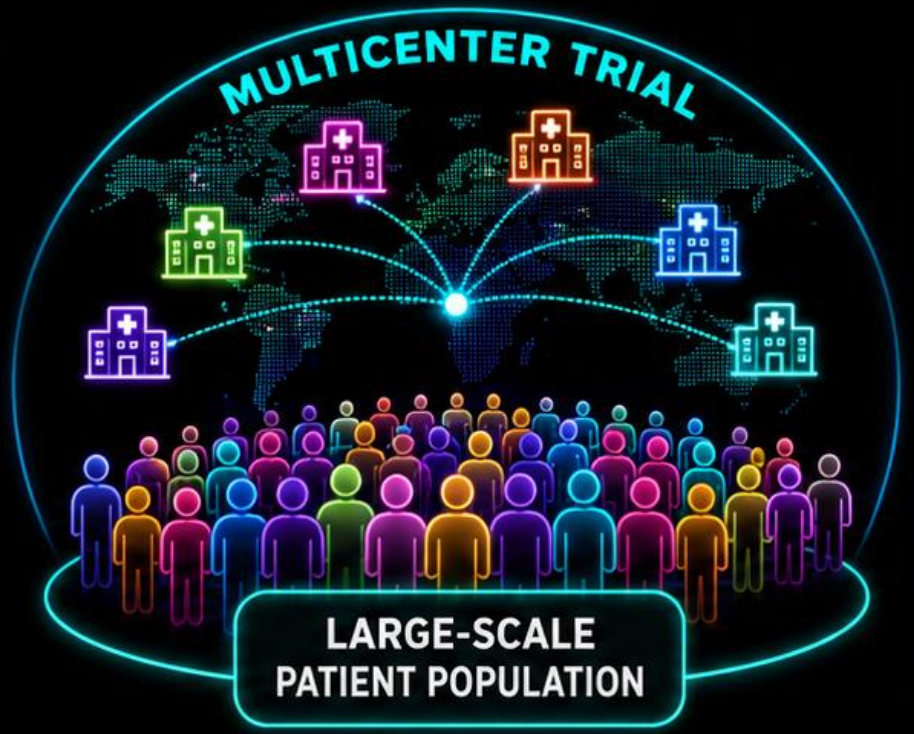
THERAPEUTIC CONFIRMATORY TRIALS

~3000 PATIENTS

Usually involves about three thousand patients to provide robust evidence.

WIDER SAFETY & TOLERABILITY

Assesses safety, tolerability, and adverse reactions on a wider scale.



THERAPEUTIC CONFIRMATION

Confirms therapeutic efficacy and benefit over risk in a large patient population.

DEFINITIVE EVIDENCE

Provides high-quality evidence for labeling and regulatory decision making.

RIGOROUS PROTOCOL → Well-designed, controlled, and randomized.

LARGE PATIENT ENROLLMENT → ~3000 patients across multiple centers.

SAFETY & EFFICACY EVALUATION → Comprehensive analysis of outcomes, safety, and tolerability.

CLINICAL STUDY REPORT → Results compiled and validated for regulatory review.

FOLLOWED BY NDA SUBMISSION

Successful completion is followed by New Drug Application submission.

PHASE III TRIALS PROVIDE DEFINITIVE EVIDENCE OF SAFETY & EFFICACY AT SCALE, PAVING THE WAY FOR REGULATORY APPROVAL AND PATIENT ACCESS.

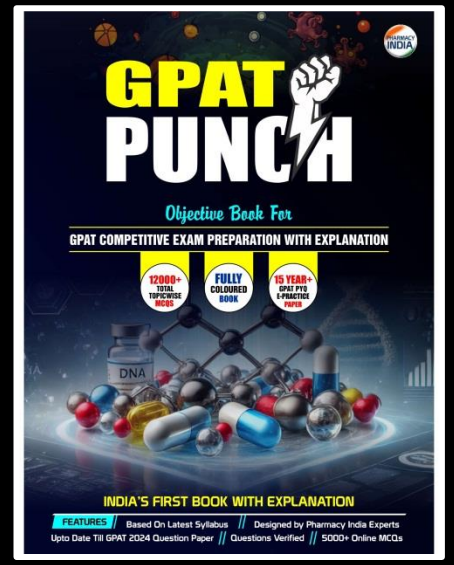
06. **The number of subjects required in a Phase I clinical trial is: [GPAT-2018]**

(a) 20 to 100

(b) Up to several hundred

(c) 300 to 3000

(d) Several thousands



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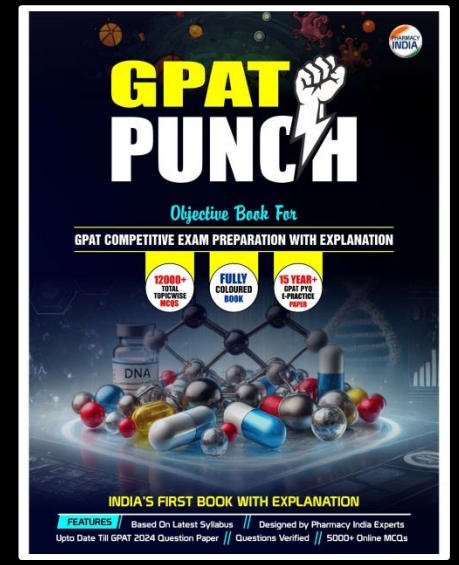


PHASE I TRIAL

FIRST-IN-HUMAN STUDY • PRIMARY FOCUS: SAFETY

20–100
SUBJECTS

USUALLY HEALTHY VOLUNTEERS

ASSESSES SAFETY
Monitors adverse events and side effects.

EVALUATES TOLERABILITY
Determines how well the drug is tolerated.

DOSE FINDING
Identifies safe dose range and maximum tolerated dose (MTD).

PHARMACOKINETICS
PK
Studies absorption, distribution, metabolism and excretion.

GOAL: DETERMINE SAFETY, TOLERABILITY, DOSE RANGE AND PHARMACOKINETICS TO GUIDE FUTURE TRIALS.

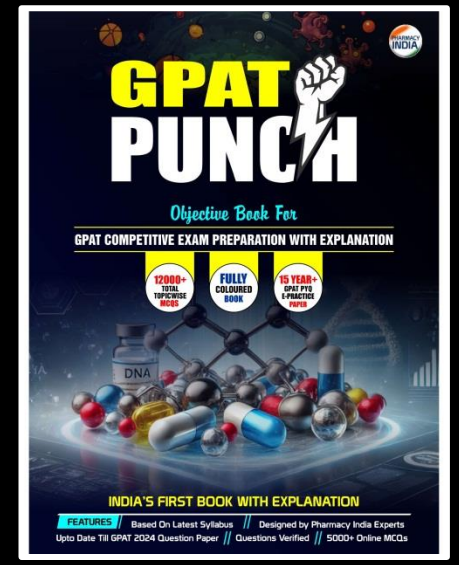
07. **Phase 0 studies mean: [GPAT-2017]**

(a) In vitro studies

(b) Part of Phase I studies of clinical trials

(c) First-in-human microdosing studies

(d) Studies carried out on small number of animals



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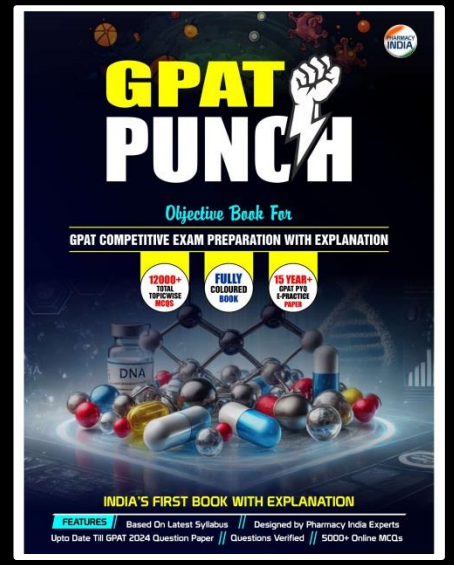
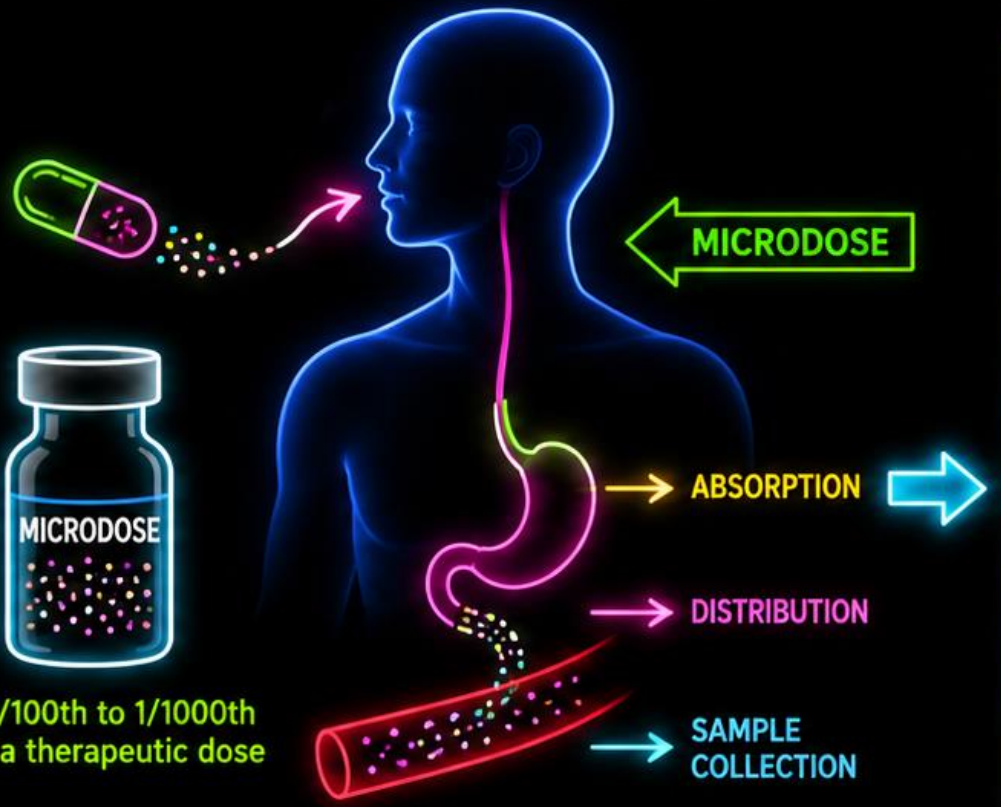


PHASE 0 STUDIES

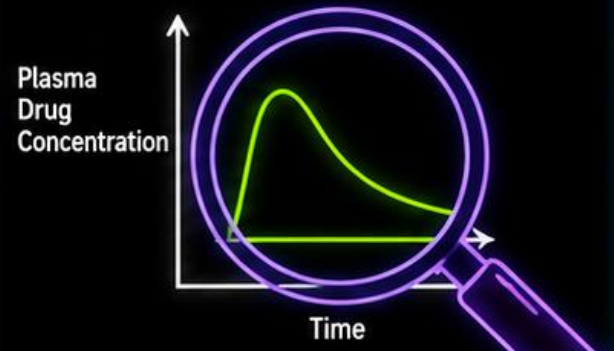
FIRST-IN-HUMAN MICRODOSING STUDIES

KEY POINTS

- FIRST-IN-HUMAN
- MICRODOSING
- VERY LOW, SUBTHERAPEUTIC DOSE
- EARLY PHARMACOKINETIC INSIGHT



EARLY PK INSIGHT



- Absorption
- Distribution
- Metabolism
- Excretion
- PK Profile & Human Biomarker Assessment

PURPOSE: To obtain early human pharmacokinetic data with minimal risk before larger clinical trials.

SAFE • ETHICAL EFFICIENT

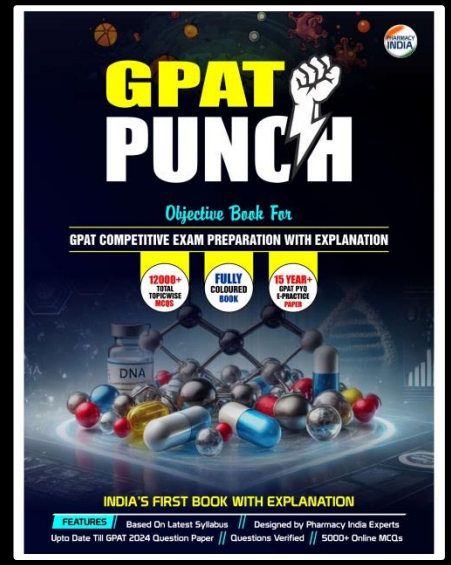
08. **In which phase of clinical trials do healthy normal human volunteers participate? [GPAT-2016]**

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV



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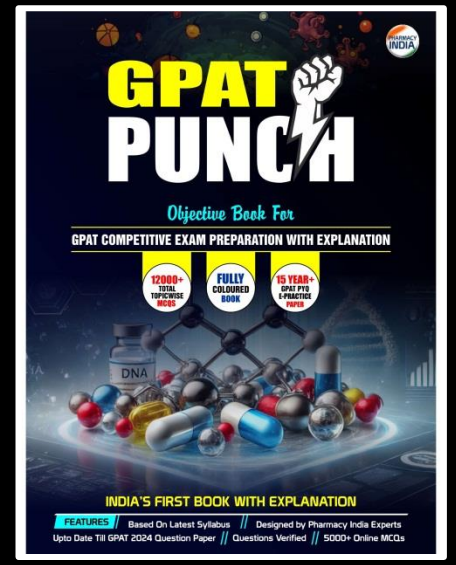


HEALTHY VOLUNTEERS IN PHASE I

HEALTHY NORMAL HUMAN VOLUNTEERS MAINLY PARTICIPATE IN PHASE I CLINICAL TRIALS.

1. **HEALTHY VOLUNTEERS**
   Healthy adults with no significant disease.
2. **INITIAL HUMAN EXPOSURE**
   First administration of the investigational drug in humans.
3. **FOCUS**
   - Safety
   - Tolerability
   - Pharmacokinetics (PK)
   - Pharmacodynamics (PD)
4. **DOSE ESCALATION**
   Start low, go slow. Increase dose in steps to find the safe range.

SAFETY FIRST
Protect today, treat tomorrow.

WHAT WE EVALUATE

SAFETY	TOLERABILITY	PK	PD
Adverse events & vital signs	How well the body handles the drug	Absorption, distribution, metabolism, excretion	Drug effect on the body/ biomarkers

HOW IT WORKS

Single or multiple dose → Careful monitoring → Samples & data collection → Analysis & safety review

GOAL: ESTABLISH **SAFETY**, UNDERSTAND **PK/PD**, AND FIND THE FOUNDATION FOR FURTHER STUDIES.

REMEMBER
Small studies.
Short duration.
Big impact.

- Builds the safety profile
- Usually 20–100 healthy volunteers
- Close medical supervision
- Informed consent is essential
- Ethics & participant safety come first

09. **The phases of clinical trials in correct order are: [GPAT-2012]**

[P] Human pharmacology

[Q] Therapeutic confirmatory trials

[R] Post-marketing trials

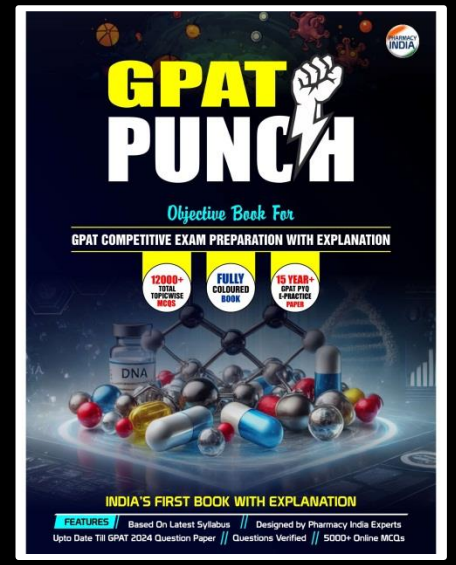
[S] Therapeutic exploratory trials

(a) P, Q, R, S

(b) P, R, Q, S

(c) P, Q, S, R

(d) P, S, Q, R



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(b) P, R, Q, S

(c) P, Q, S, R

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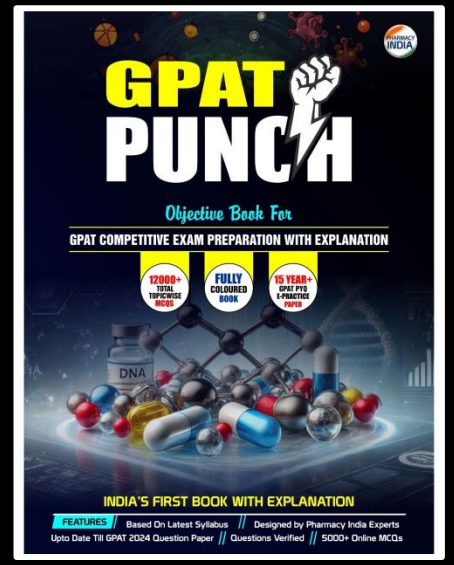


ORDER OF CLINICAL TRIAL PHASES

1 PHASE I
HUMAN PHARMACOLOGY

- First use in humans
- **20–100** healthy volunteers
- Assess safety, tolerability & pharmacokinetics
- Determine safe **dose range**

SAFETY FIRST

2 PHASE II
THERAPEUTIC EXPLORATORY

- First use in patients
- **100–300** patients
- Evaluate effectiveness
- Assess side effects
- Find **optimal dose**

EFFICACY & DOSE FINDING

3 PHASE III
THERAPEUTIC CONFIRMATORY

- Large scale studies
- **300–3,000+** patients
- Confirm effectiveness
- Monitor side effects
- Compare with **standard treatment / placebo**

CONFIRM & COMPARE

4 PHASE IV
POST-MARKETING

- After regulatory approval
- **Thousands** to **millions** of patients
- Long-term safety
- Real-world effectiveness
- Detect **rare / late** adverse effects

MONITOR & IMPROVE

KEY PROGRESSION

Ensure Safety → Explore Effectiveness → Confirm Benefit → Monitor in Real World

STEPWISE EVIDENCE
FROM FIRST-IN-HUMAN TO REAL-WORLD CARE

SAFE TODAY. EFFECTIVE TOMORROW. BETTER FOR EVERY PATIENT.

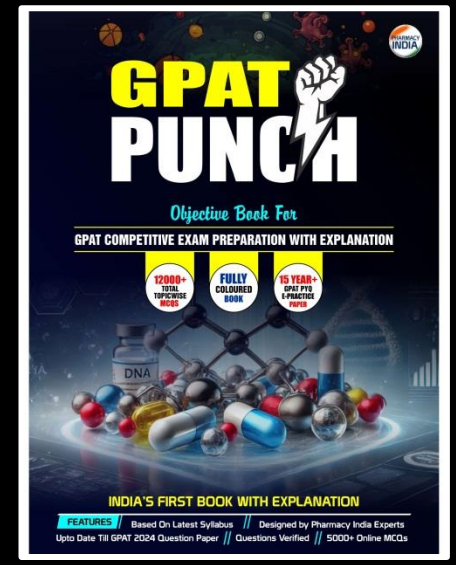
10. **Geriatric populations should be included in which phase of clinical trials? [GATE-2010]**

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV



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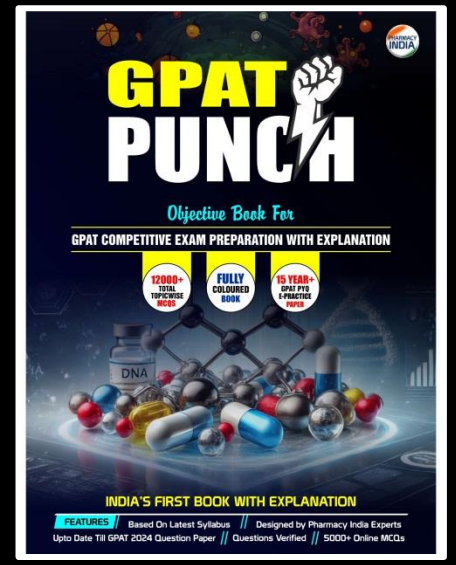


GERIATRIC POPULATION

Elderly patients have unique needs.
They deserve dedicated evaluation in clinical research.

INCLUDED IN PHASE IV

Geriatric populations are especially included in Phase IV studies.

REAL-WORLD ELDERLY SAFETY

Evaluates medicine safety in everyday clinical practice among elderly.

MONITORS ADRs AND TOLERABILITY

Detects and monitors adverse drug reactions (ADRs) and tolerability in older adults.

IMPORTANT IN COMORBIDITY & POLYPHARMACY

Elderly often have multiple diseases and take multiple medications.

DIVERSE AND REPRESENTATIVE

Ensures inclusion of diverse elderly (age, gender, ethnicity, frailty levels).

IMPROVES OUTCOMES AND DECISIONS

Provides robust real-world evidence to guide safer and better treatment decisions.

PHASE IV

FOCUS:
REAL-WORLD SAFETY
IN ELDERLY PATIENTS

SAFETY FIRST
Protecting our elderly, always.

RESPECT & DIGNITY
Every elder deserves evidence-based care.

BETTER CARE
Better data leads to better health.

SMARTER MEDICINE
Right treatment for the right patient.

REAL IMPACT
Real-world evidence. Real patient benefit.

REMEMBER

Phase IV studies ensure that medicines remain SAFE, EFFECTIVE, and SUITABLE for our elders in the real world.

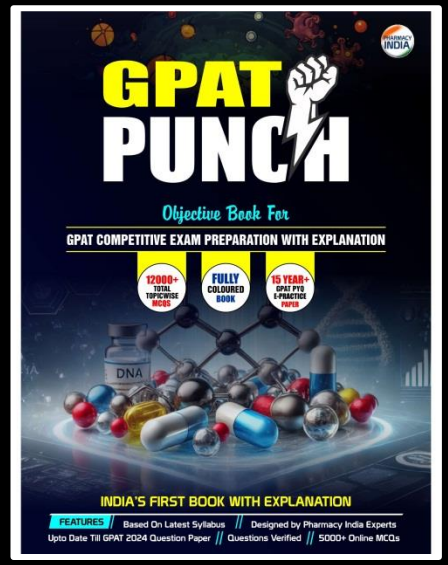
11. **Phase I clinical studies of a drug under development are generally carried out on: [GATE-2009]**

(a) At least 10,000 people from different ethnic communities and wide age groups

(b) 500–1000 patients suffering from the disease for which the drug is being developed

(c) A small group of 20–100 healthy volunteers

(d) Reliable in vitro cell lines derived from diseased patients



11. **Phase I clinical studies of a drug under development are generally carried out on: [GATE-2009]**

(a) At least 10,000 people from different ethnic communities and wide age groups

(b) 500–1000 patients suffering from the disease for which the drug is being developed

(c) A small group of 20–100 healthy volunteers

(d) Reliable in vitro cell lines derived from diseased patients

PHASE I CLINICAL STUDIES

Healthy Volunteers

- First-in-human clinical testing
- Usually 20-100 healthy volunteers
- Checks safety and tolerability
- Studies pharmacokinetics and dose range
- Builds the initial safe-use profile

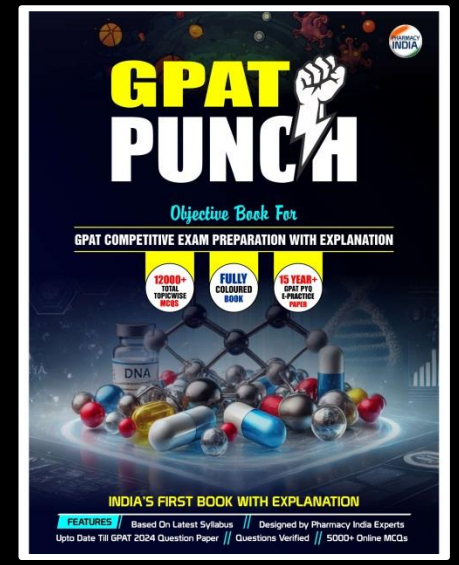
12. **Pharmacovigilance is done for monitoring:**

(a) Drug price

(b) Unethical practices

(c) Drug safety

(d) Pharmacology students



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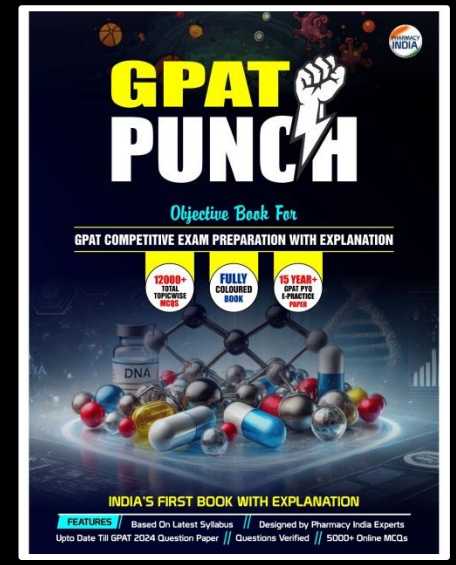


PHARMACOVIGILANCE

Monitoring Drug Safety

- Detects adverse drug reactions (ADRs)
- Tracks risk-benefit after marketing
- Improves patient safety
- Supports rational use of medicines
- Continuous safety reporting system

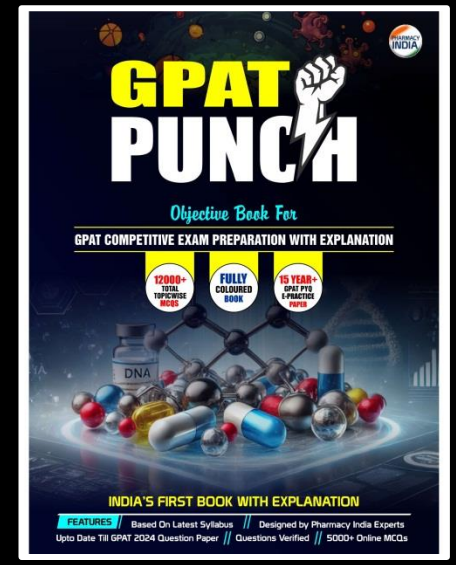
13. **Post-marketing surveillance is a part of which phase of clinical trial?**

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV



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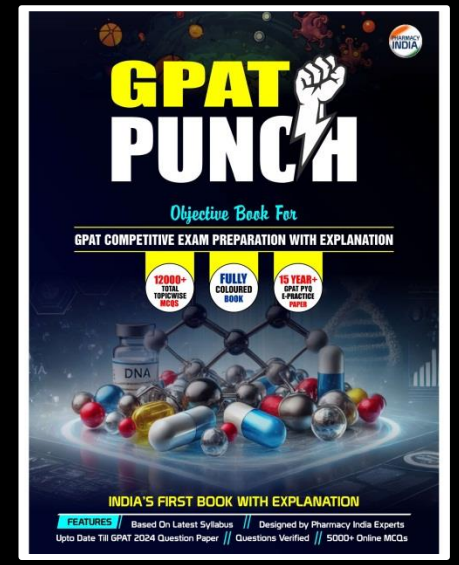


POST-MARKETING SURVEILLANCE

Part of Phase IV

- Begins after drug approval
- Monitors real-world safety
- Detects rare and long-term ADRs
- Covers large patient populations
- Helps update warnings and labeling

SAFETY MONITORING

ADVERSE EVENT REPORTS

DATA COLLECTION → ANALYSIS → SAFETY ASSESSMENT → UPDATED WARNINGS & LABELING → SAFER PATIENTS

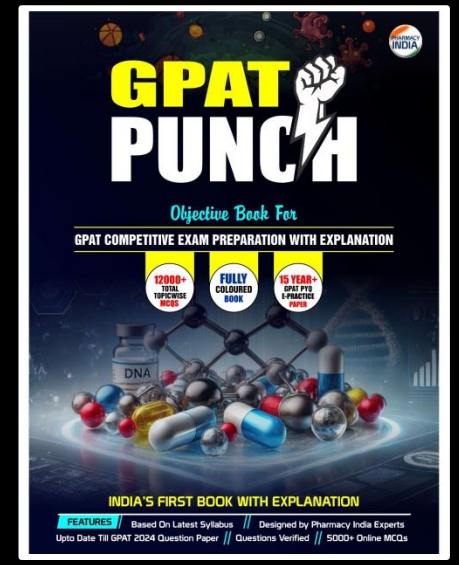
14. Study of drugs in humans is termed:

(a) Pharmacy

(b) Clinical pharmacology

(c) Experimental pharmacology

(d) Toxicology



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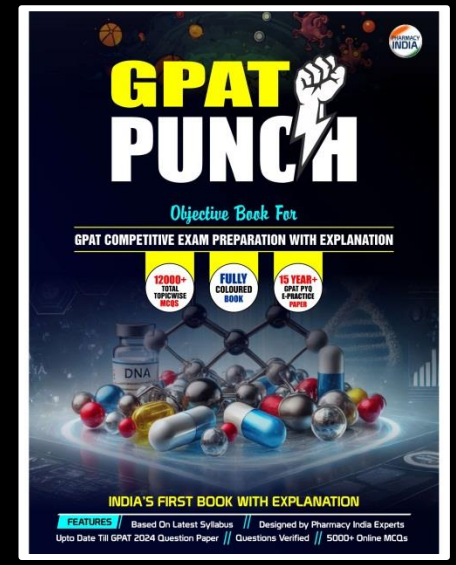
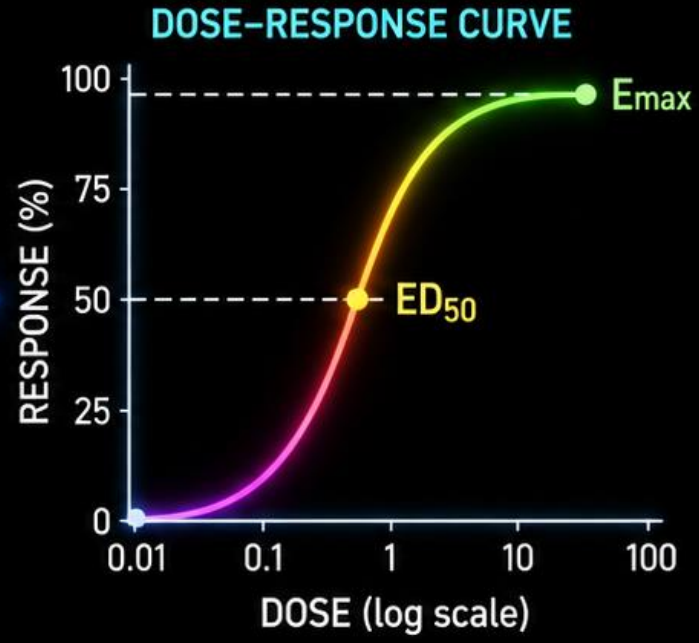


CLINICAL PHARMACOLOGY

Study of Drugs in Humans

- Studies drug effects in human beings
- Links pharmacology with clinical medicine
- Examines efficacy, safety and dose-response
- Includes pharmacokinetics and pharmacodynamics
- Guides rational drug therapy



PHARMACOKINETICS (PK)

ABSORPTION → DISTRIBUTION → METABOLISM → EXCRETION

What the body does to the drug

PHARMACODYNAMICS (PD)

DRUG → RECEPTOR BINDING → RESPONSE

What the drug does to the body

SAFE • EFFECTIVE RATIONAL THERAPY

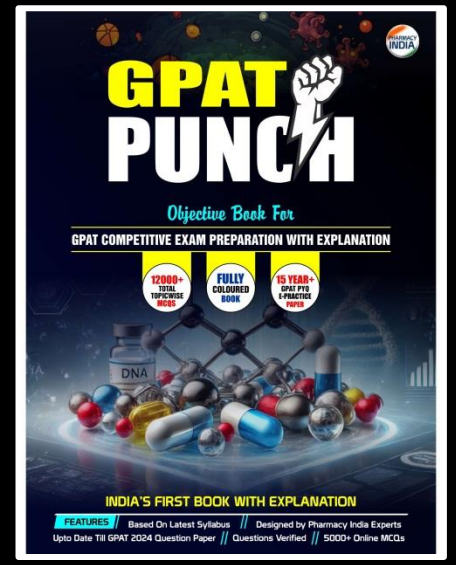
15. **Design of the study aimed to assess the maximum tolerable dose of a new drug is best described as:**

(a) Case-control study

(b) Phase II randomized controlled trial

(c) Phase I trial

(d) Phase III randomized controlled trial



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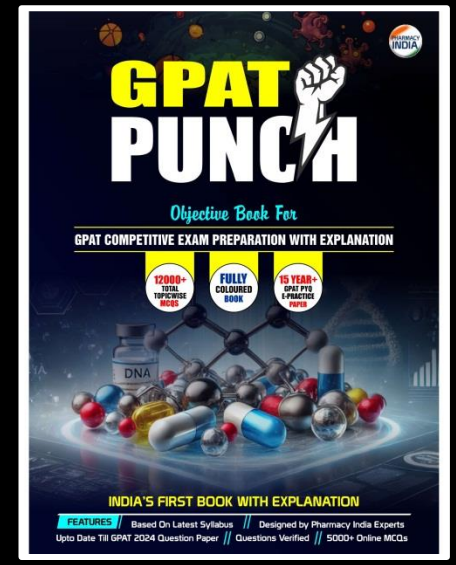
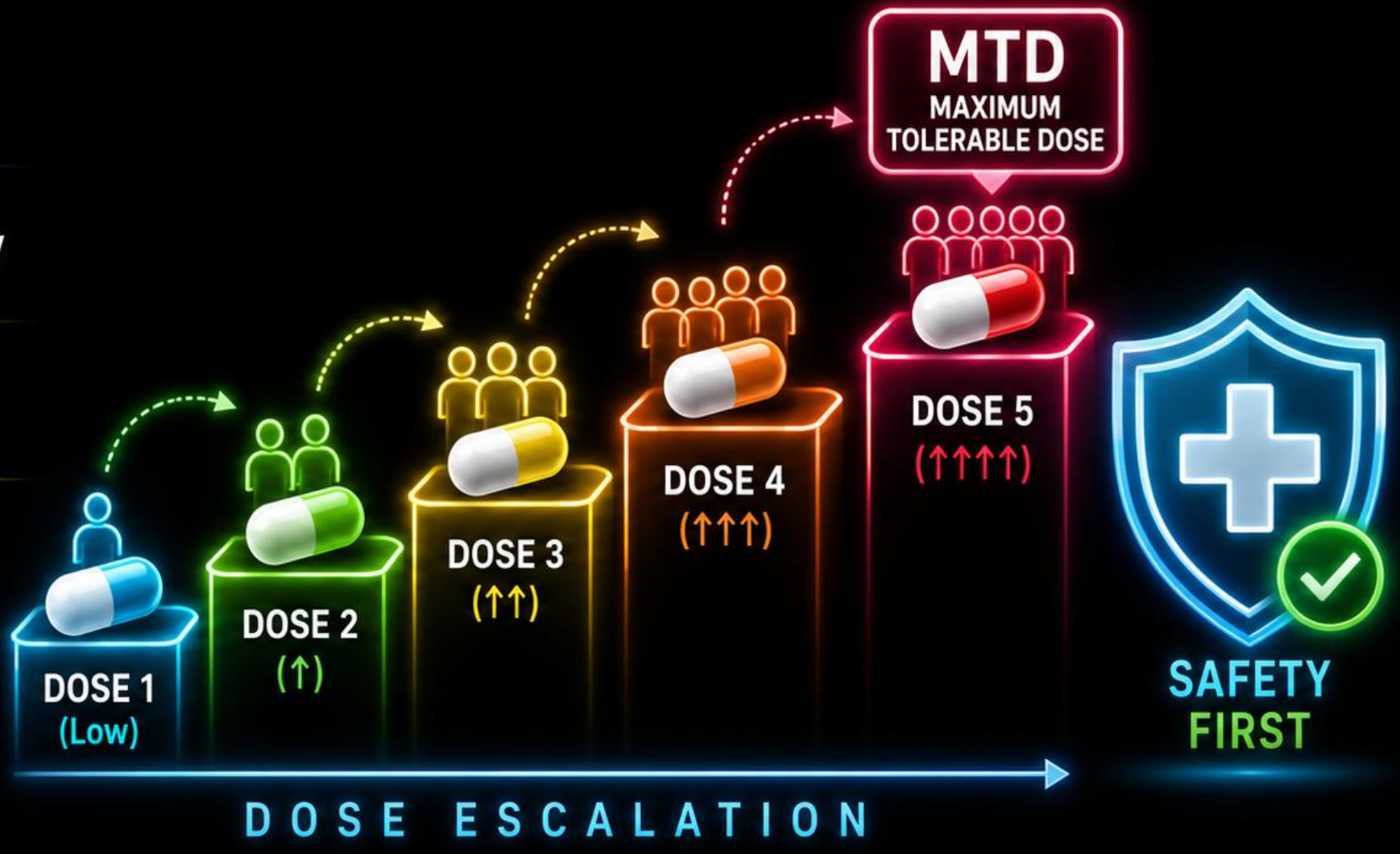


MAXIMUM TOLERABLE DOSE

Assessed in Phase I Trials

- Start with a low dose
- Increase dose gradually
- Monitor safety and tolerability
- Identify dose-limiting toxicity
- Define the maximum tolerable dose (MTD)



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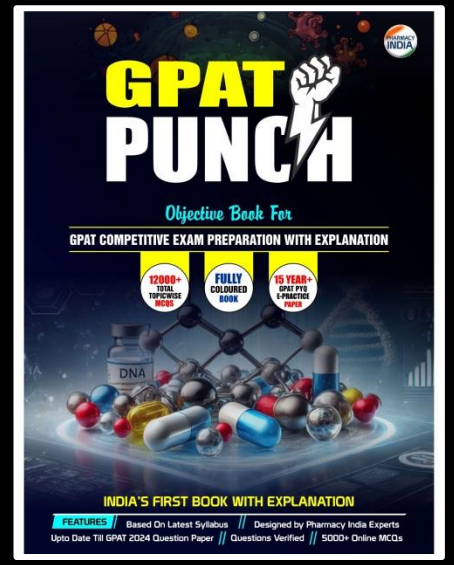
(d) Phase IV



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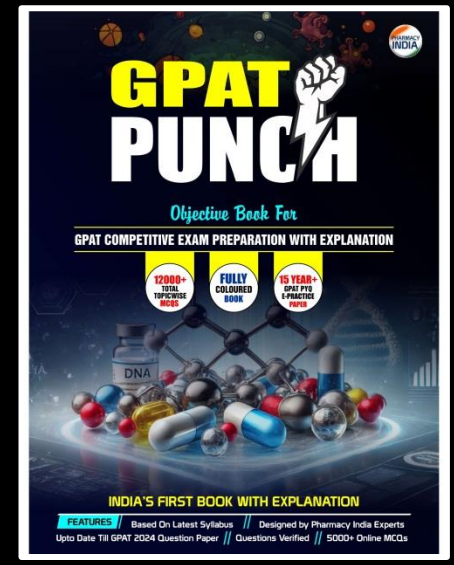


PHASE III COMPARATIVE TRIALS

New Drug vs Standard Drug

- Compares efficacy with existing treatment
- Uses large patient groups
- Randomized controlled design is common
- Confirms therapeutic benefit
- Supports regulatory approval

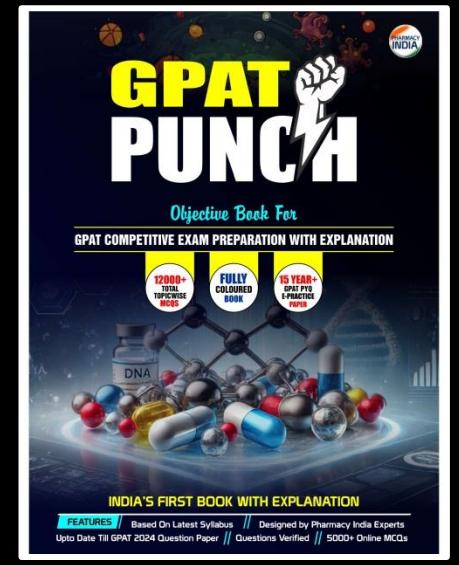
17. **Good Clinical Practice is not required in:**

(a) Preclinical phase

(b) Phase I trial

(c) Phase II studies

(d) Phase IV studies



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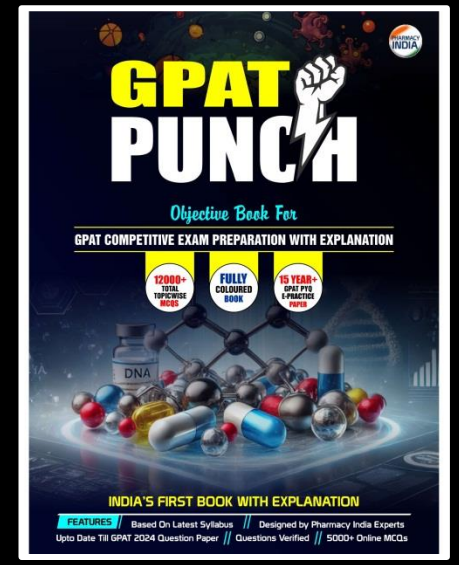


GOOD CLINICAL PRACTICE (GCP)

Not for Preclinical Phase

- GCP applies to clinical trials in humans
- Ensures ethics, data quality and participant safety
- Used in Phase I, II, III and IV studies
- Preclinical work follows GLP, not GCP
- Human studies require strict GCP compliance

PARTICIPANT SAFETY

ETHICS

DATA QUALITY

INTEGRITY

GLP	VS	GCP
Good Laboratory Practice		Good Clinical Practice
Preclinical (Non-human) Laboratory Studies		Clinical (Human) Studies

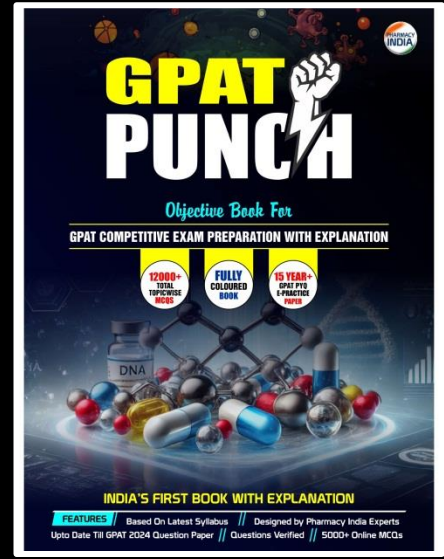
18. The aim of post-marketing studies is:

(a) Efficacy of the drug only

(b) Dosage of the drug only

(c) Absorption, distribution, binding and storage of drug

(d) Safety and comparison with other medicines



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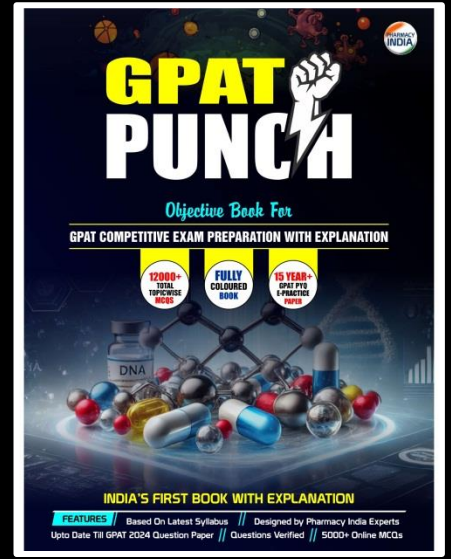
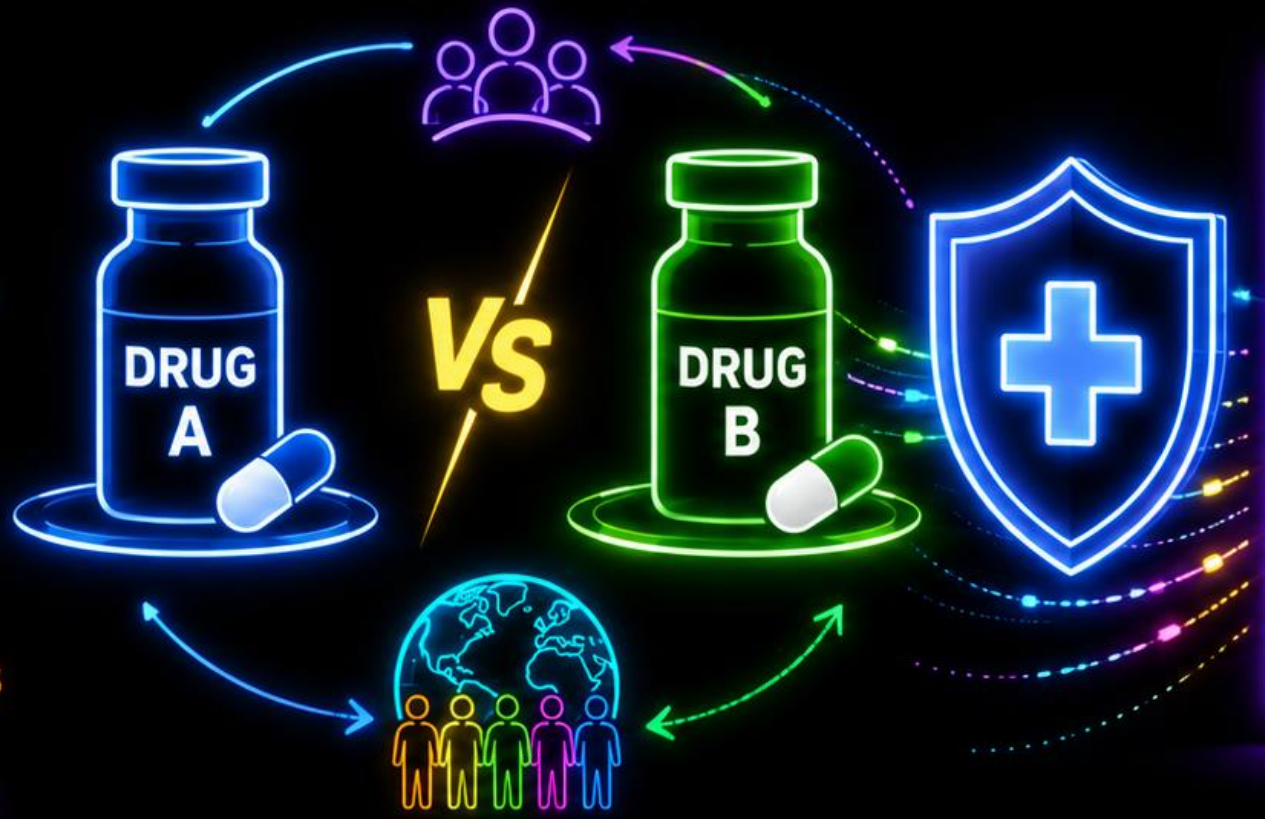


POST-MARKETING STUDIES

Main Aim

- Focus on safety in real-world use
- Compare the drug with other medicines
- Reveal rare, delayed and long-term adverse effects
- Assess performance in special populations
- Improve labeling and clinical guidelines



REAL-WORLD EVIDENCE → DETECT RARE & LONG-TERM RISKS → ONGOING MONITORING → BETTER PATIENT OUTCOMES → IMPROVED LABELING & GUIDELINES

19. **Monitoring of plasma drug concentration is required while using: [GPAT-2024]**

(a) Antihypertensive drugs

(b) Levodopa

(c) Lithium carbonate

(d) MAO inhibitors

19. **Monitoring of plasma drug concentration is required while using: [GPAT-2024]**

(a) Antihypertensive drugs

(b) Levodopa

(c) Lithium carbonate

(d) MAO inhibitors

THERAPEUTIC DRUG MONITORING

Lithium Carbonate

- Lithium has a narrow therapeutic index
- Plasma level monitoring is essential
- Prevents toxicity and underdosing
- Helps individualize dose
- Important in long-term therapy

THERAPEUTIC RANGE
(Plasma Lithium Level)

- **TOXIC** > 1.5 mEq/L
- **0.6 – 1.2 mEq/L** → **THERAPEUTIC**
- **SUBTHERAPEUTIC** < 0.6 mEq/L

MOOD STABILIZER | PREVENTS RELAPSE | RENAL CLEARANCE | THYROID EFFECTS | Hydration Important

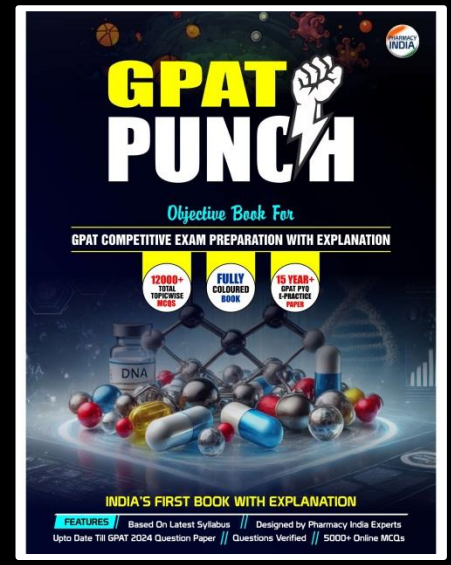
20. Pharmacogenetics deals with:

(a) Clinically significant genetically mediated variations in drug response

(b) Harmful effects on foetus

(c) Drug-induced genetic defect

(d) Development of drugs by recombinant DNA technology



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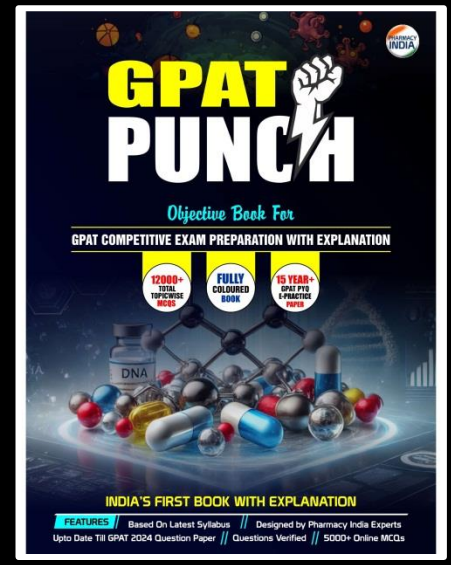

PHARMACOGENETICS

Genes Influence Drug Response

- Studies genetically mediated variation in drug response
- Explains why patients respond differently
- Can affect efficacy and toxicity
- Supports personalized medicine
- Improves safety and treatment outcomes

DNA
(Genetic Variation)

GENES
(Variants)

DRUG
(Medication)

GOOD RESPONSE
Optimal efficacy
Minimal side effects

REDUCED RESPONSE
Lower efficacy
May need dose adjustment

POOR RESPONSE
Little or no benefit
Consider alternative drug

ADVERSE RESPONSE
Increased risk of toxicity
Higher side effects

RIGHT DRUG. RIGHT DOSE. RIGHT PATIENT.

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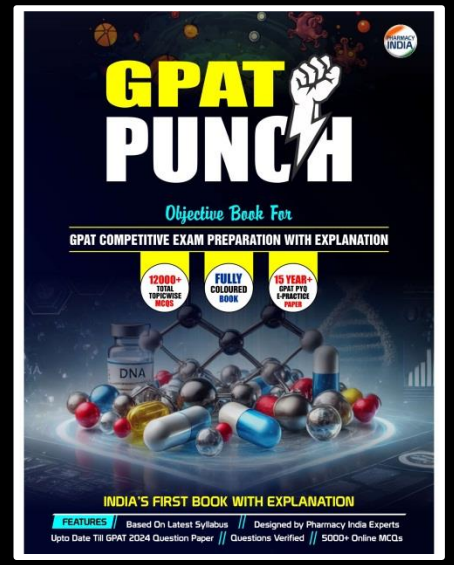
21. **Drug tolerance due to decreased availability of drug at receptor site because of hepatic enzyme induction is known as:**

(a) Cellular tolerance

(b) Drug dispositional tolerance

(c) Physiological tolerance

(d) Pseudo tolerance



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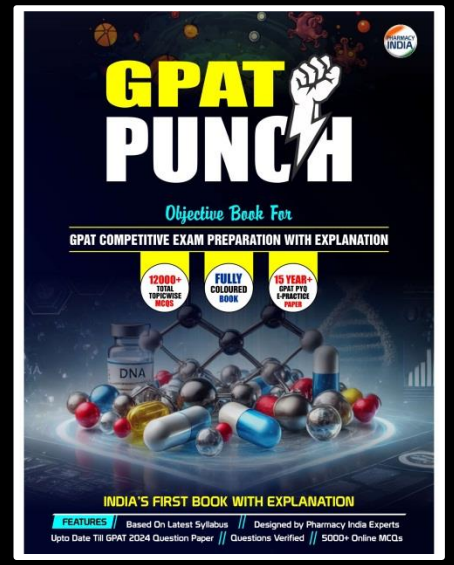
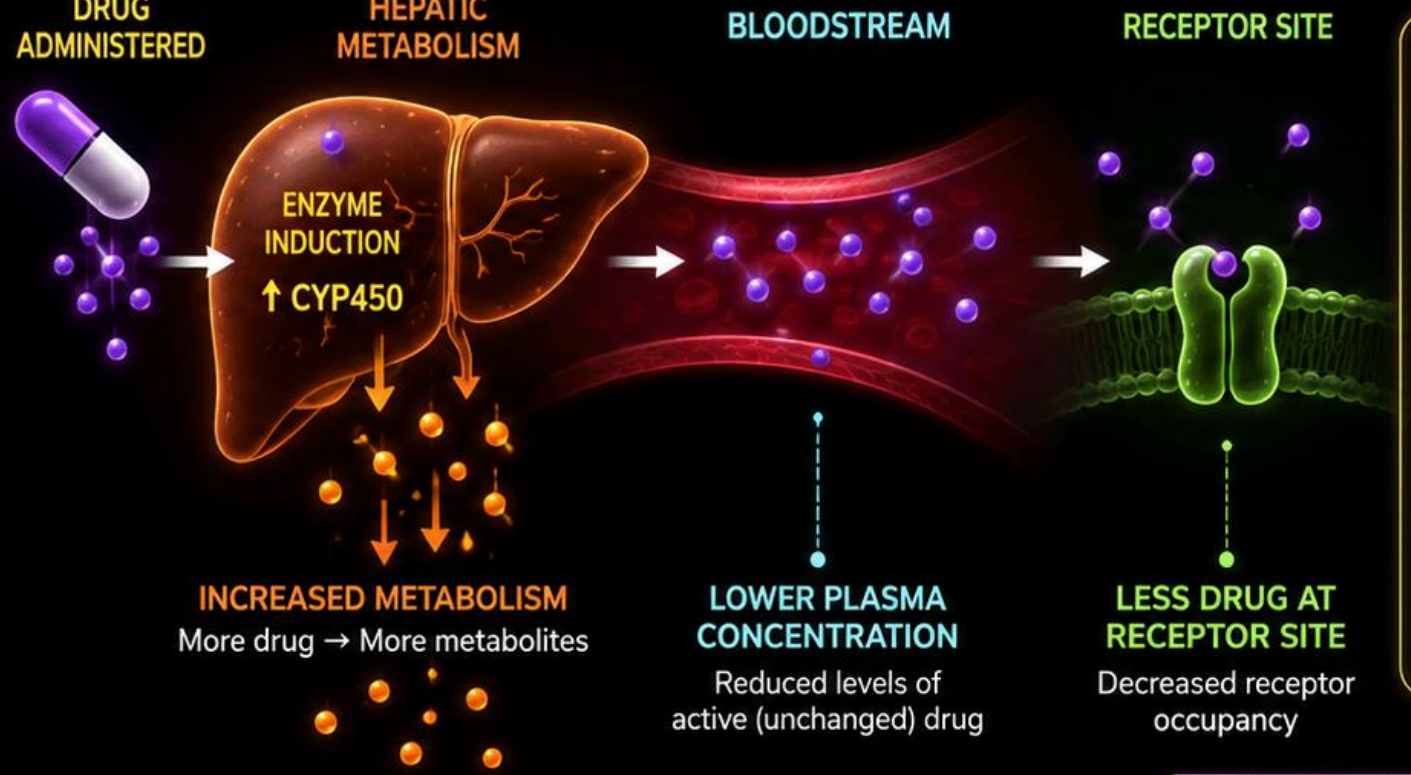


Drug Dispositional Tolerance

Reduced response due to lower drug availability at the receptor site

1. **Usually caused by hepatic enzyme induction**
   Repeated or chronic drug use induces drug-metabolizing enzymes (e.g., CYP450)
2. **Faster metabolism**
   Drug is broken down more quickly in the liver
3. **Lowers plasma concentration**
   Less unchanged drug remains in the bloodstream
4. **Less drug reaches the target**
   Fewer molecules reach the receptor site
5. **Effect decreases**
   Reduced pharmacologic response at usual dose



This is a PHARMACOKINETIC type of tolerance

- ✓ Change in ADME (Absorption, Distribution, Metabolism, Excretion)
- ✓ Drug amount at the receptor site decreases
- ✓ Overcome by increasing dose or reducing enzyme induction

EXAMPLES (Enzyme Inducers)

Rifampin · Phenytoin · Carbamazepine · St. John's Wort · Chronic Smoking

KEY TAKEAWAY

In drug dispositional tolerance, the body removes the drug faster, so less drug reaches the receptor and the effect falls.

DIFFERENT FROM CELLULAR TOLERANCE

Cellular (pharmacodynamic) tolerance involves changes at the receptor or post-receptor level, where receptor responsiveness is altered.

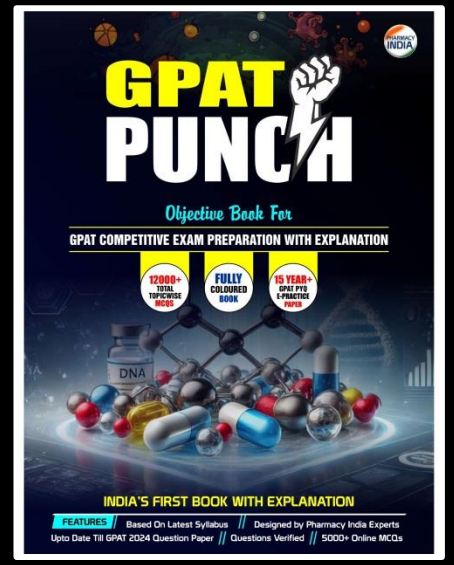
22. When there is a gradual decrease in response to a drug taking days or weeks to develop, the phenomenon is called:

(a) Desensitization

(b) Tachyphylaxis

(c) Tolerance

(d) Idiosyncrasy



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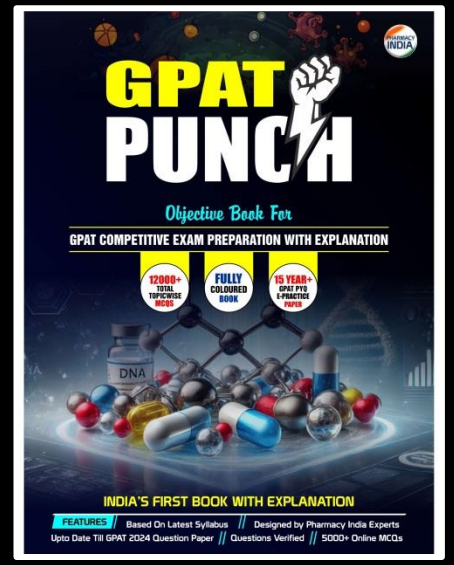


Tolerance

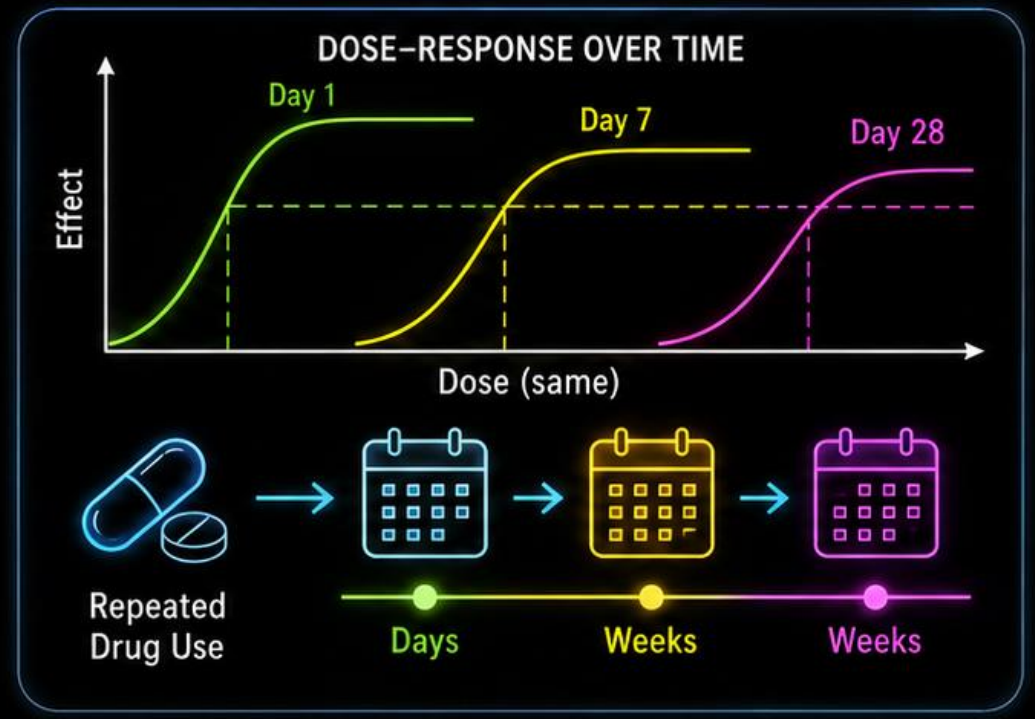
A state of reduced responsiveness to a drug after repeated use

DEFINITION
Gradual decrease in response after repeated drug use.

TIME COURSE
Usually develops over days to weeks.

REDUCED EFFECT
The same dose produces a smaller effect.

HIGHER DOSE NEEDED
A larger dose may be needed to get the same response.



Tachyphylaxis = rapid tolerance (minutes to hours) ≠ **Tolerance** = slow development (days to weeks)

MECHANISMS
May be due to pharmacokinetic or pharmacodynamic adaptation.

RECEPTOR DOWNREGULATION
Fewer receptors → less response

POST-RECEPTOR CHANGES
Reduced signal transduction or sensitivity

INCREASED DRUG METABOLISM
Enzyme induction → lower drug levels

INCREASED DRUG EFFLUX
Enhanced transport reduces intracellular drug

NEURAL ADAPTATION
CNS adapts to persistent drug presence

EXAMPLES
- Opioids (analgesia, euphoria)
- Nitrates (vasodilation)
- β_2-agonists (bronchodilation)
- Sedatives / Hypnotics

Key Point: With repeated use, the body adapts → same dose, less effect → higher dose needed for same response.

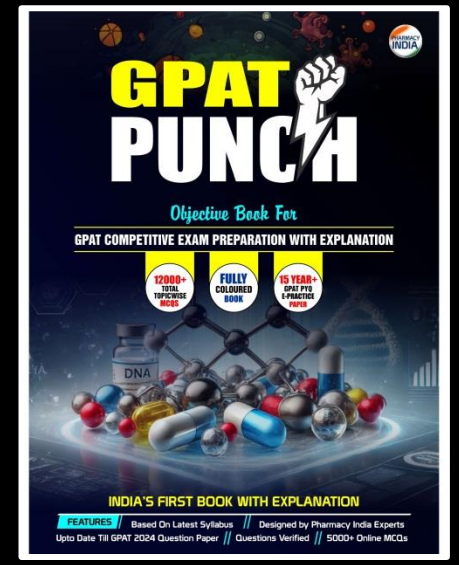
23. **When an inert chemical produces psychopharmacological effect, it is called:**

(a) Prodrug

(b) Placebo

(c) Idiosyncratic response

(d) Adjuvant



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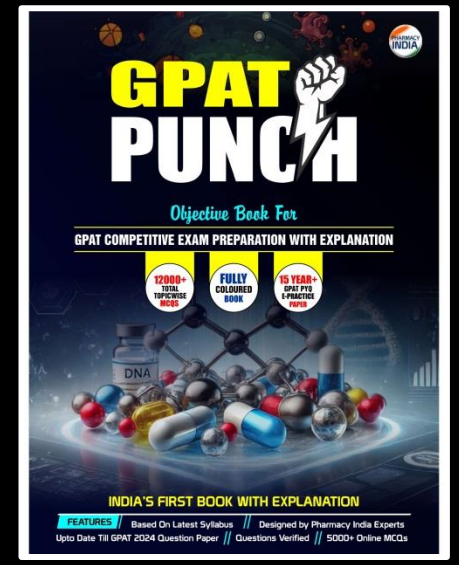


PLACEBO EFFECT

THE POWER OF BELIEF CAN HEAL

PLACEBO DEFINITION

- Placebo = a **pharmacologically inert substance**
- No specific therapeutic activity

HOW IT WORKS

- It can still produce **perceived benefit** or **side effects**
- Response occurs due to **expectation, conditioning, and belief**

MECHANISMS

- Release of **endogenous opioids, dopamine**
- Modulation of pain **pathways**
- Changes in **autonomic** and **immune responses**

PSYCHOLOGICAL RESPONSE
Expectation • Conditioning • Belief

PHARMACOLOGICALLY INERT SUBSTANCE
No active drug effect

Mind–body interaction modulates **perception** of symptoms

PERCEIVED BENEFIT

PERCEIVED SIDE EFFECTS

RESEARCH & CLINICAL USE

- Useful as a comparator in **clinical trials**
- Helps determine the **true effect** of a drug
- Account for placebo response in outcomes

APPLICATIONS

- **Pain management**
- **Depression, anxiety**
- **Irritable bowel syndrome**
- **Functional disorders**
- Supportive care

WHY IT MATTERS

- Demonstrates the **mind–body influence** on symptoms
- Enhances **patient** care through **empathy**, communication & trust

KEY TAKEAWAYS

- Inert pill, real response
- **Expectation** drives effect
- **Mind–body** connection
- Can cause **benefits** or side effects
- **Essential in evidence-based** medicine

Remember: Belief can be a powerful medicine. Use it **ethically**. Communicate **clearly**. Build **trust**.

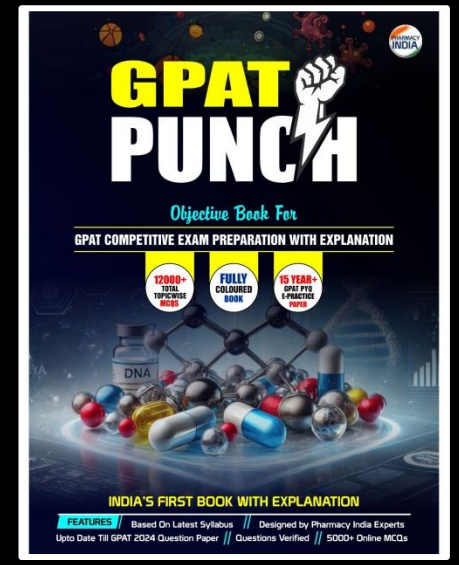
24. **Which statement about acidic drugs is true?**

(a) They are best absorbed in acidic medium

(b) They are best absorbed in alkaline medium

(c) They are not absorbed in acidic medium

(d) They bind to alpha-1 acid glycoprotein mainly



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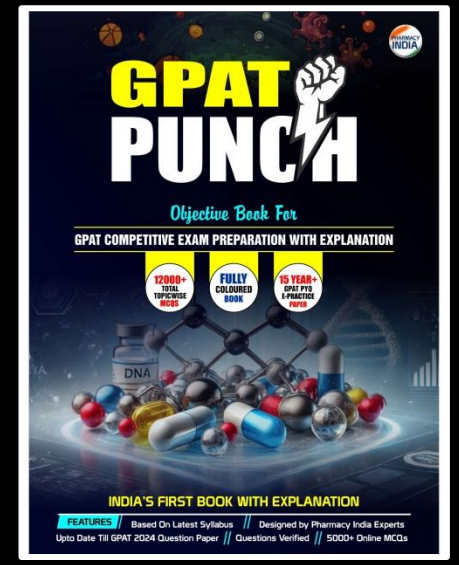


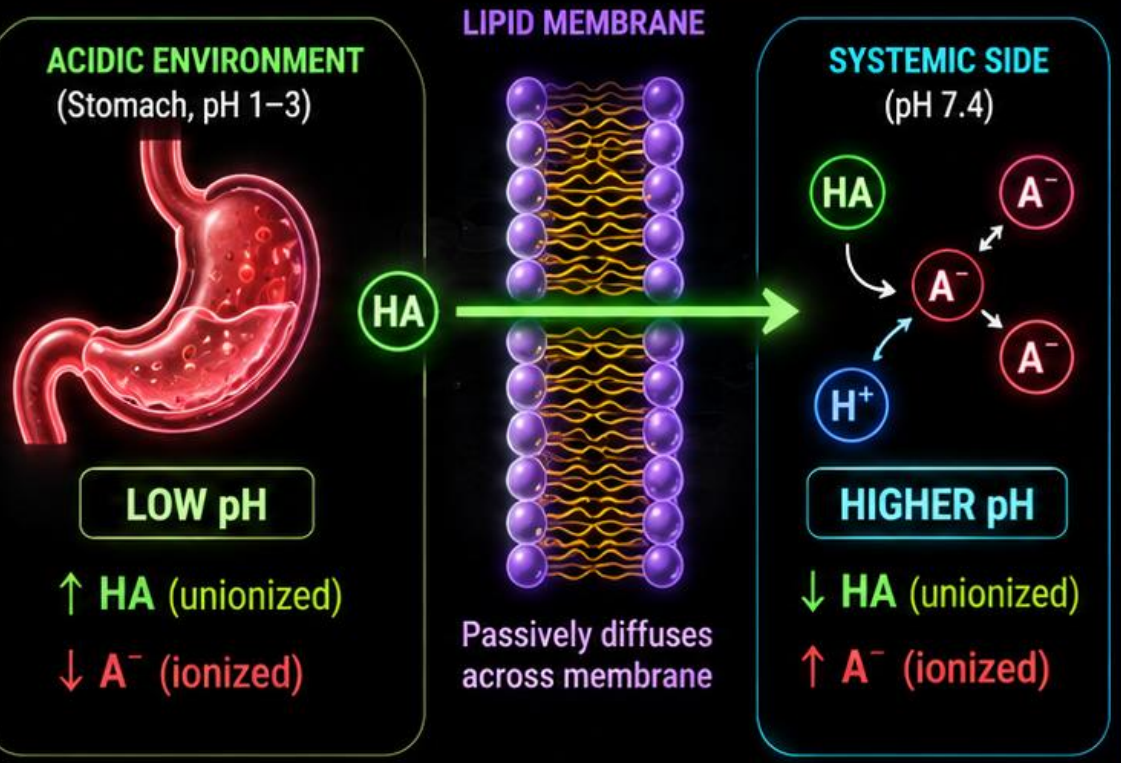
Absorption of Acidic Drugs

Principle: pH–Partition (Ionization) Hypothesis

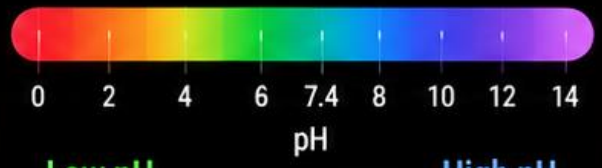
1. Weak acidic drugs are **better absorbed** in **acidic medium**
2. In low pH they remain more **unionized**
3. Unionized form crosses lipid membranes **more easily**
4. This explains the classic absorption behavior of **weak acids**

IONIZATION OF WEAK ACID

$$HA \text{ (unionized)} \rightleftharpoons H^+ + A^- \text{ (ionized)}$$



pH–IONIZATION RELATIONSHIP



Low pH → more HA (unionized)

High pH → more A^- (ionized)

KEY TAKEAWAY

Acidic medium favors unionized HA → better membrane permeation → **higher absorption**

EXAMPLE

Aspirin (acetylsalicylic acid)

- Weak acidic drug (pKa ≈ 3.5)
- Better absorbed in stomach
- Absorption decreases as pH rises

Clinical Relevance: - Antacids & ↑ gastric pH can reduce absorption of weak acidic drugs. | **Remember:** Unionized form crosses, Ionized form stays.

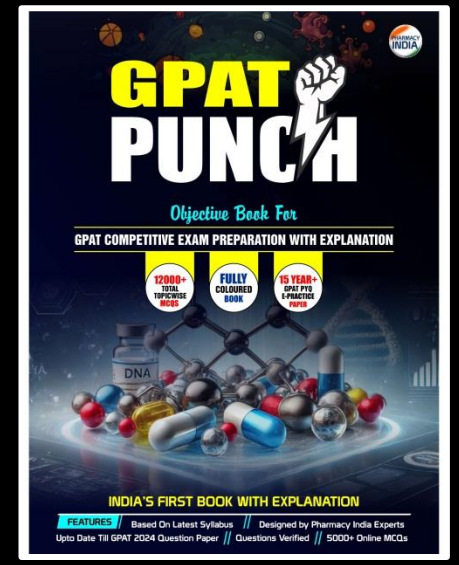
25. A highly ionized drug:

(a) Is excreted mainly by kidney

(b) Can cross placental barrier easily

(c) Is well absorbed from intestine

(d) Accumulates in cellular lipids



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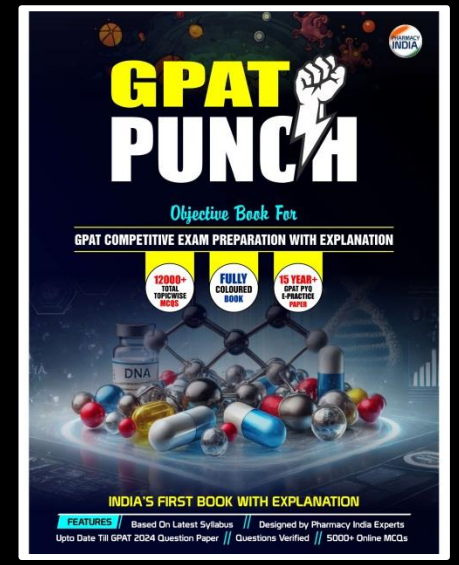
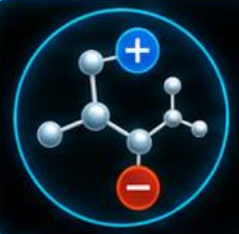
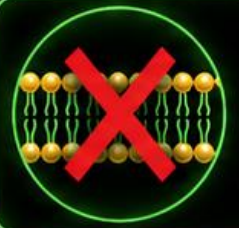


Highly Ionized Drugs

Highly ionized drugs exist mostly in charged form at physiological pH.

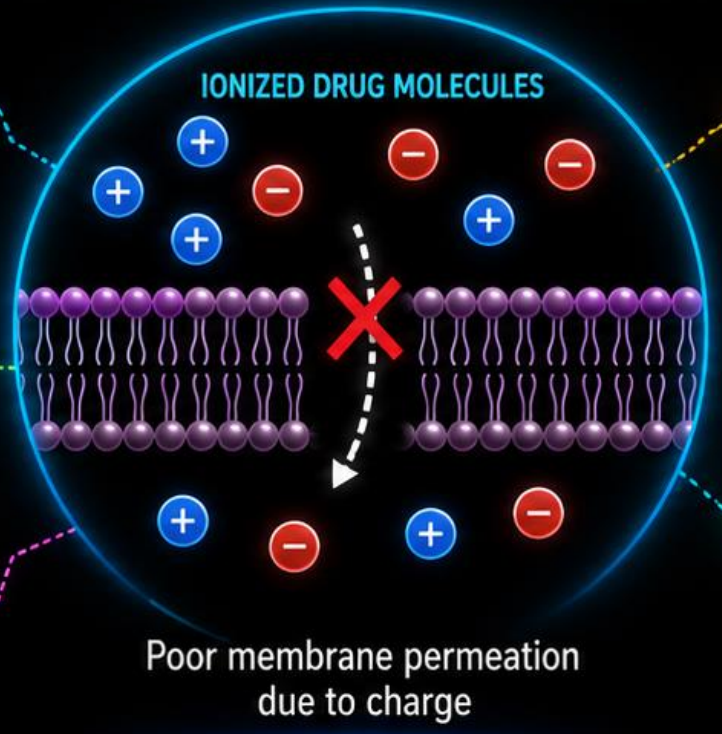


Highly ionized drugs are water-soluble and poorly lipid-soluble



They cross biological membranes poorly

Absorption from intestine is poor



Poor membrane permeation due to charge

Placental and tissue penetration is limited

- Crosses placenta poorly
- Limited entry into CNS (BBB)

Renal tubular reabsorption is low, so they are excreted mainly by kidney

- Remain in tubular fluid
- High renal clearance

PHARMACOLOGIC IMPLICATIONS

Low oral bioavailability → Often require parenteral use → Limited distribution to tissues & CNS → Shorter duration → Rapid renal elimination

Degree of ionization (governed by pKa and pH) determines **ADME** properties of drugs.

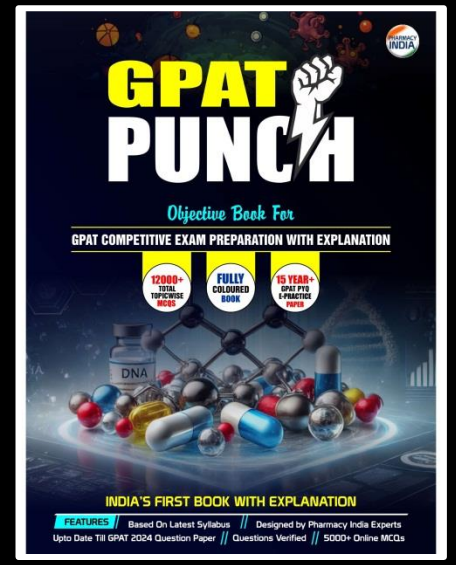
26. **All of the following statements regarding bioavailability are true except:**

(a) It is the fraction of unchanged drug that reaches systemic circulation

(b) Oral bioavailability can be calculated by comparing AUC after oral and IV administration

(c) Low oral bioavailability always and necessarily means poor absorption

(d) Bioavailability can be determined from plasma concentration or urinary excretion data



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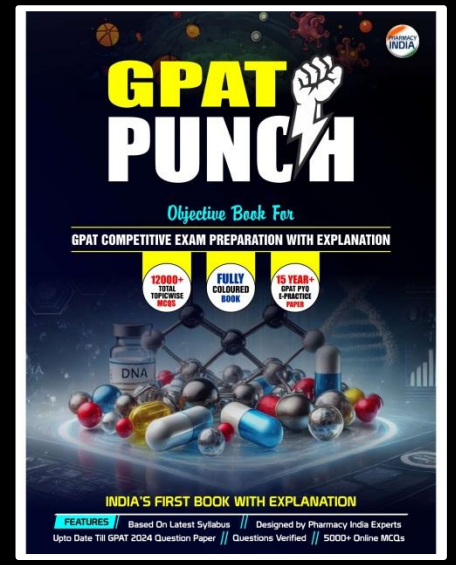


Bioavailability – Key Point

Bioavailability is the fraction of unchanged drug reaching systemic circulation

DEFINITION
Extent (F) to which active moiety reaches systemic circulation unchanged.

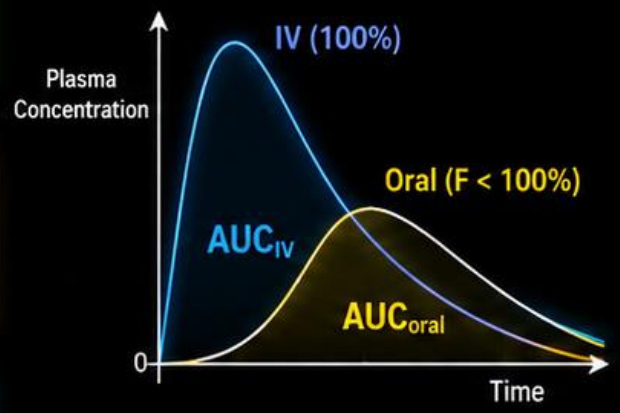
RELATIVE CONCEPT
Compares extravascular route (e.g., oral) with IV (F = 1 or 100%).

ESTIMATION
Can be estimated from plasma concentration or urinary excretion data.

CLINICAL IMPORTANCE
Guides dose selection, formulation design & therapeutic outcomes.

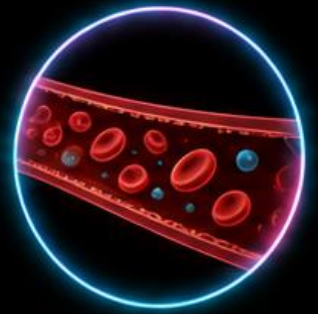
REMEMBER
High absorption ≠ High bioavailability

ORAL BIOAVAILABILITY COMPARED WITH IV USING AUC

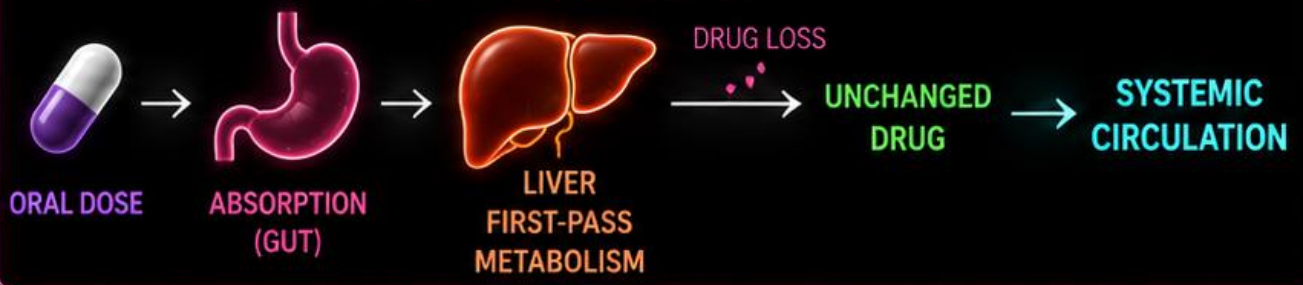


$$F(\text{oral}) = \frac{AUC_{oral}}{AUC_{IV}} \times \frac{Dose_{IV}}{Dose_{oral}}$$

SYSTEMIC CIRCULATION



FIRST-PASS METABOLISM



LOW ORAL BIOAVAILABILITY
Does not always mean poor absorption.
May be due to extensive first-pass metabolism or poor stability.

FIRST-PASS EFFECT
Metabolism in the gut wall and liver before the drug reaches systemic circulation reduces F.

FACTORS AFFECTING F
- Solubility & permeability
- Stability in GI fluids
- Transporters (P-gp)
- First-pass metabolism
- Food & pH

TYPICAL F (ORAL)
- High: > 70%
- Moderate: 30–70%
- Low: < 30%

KEY TAKEAWAY | Oral dose → Absorption (Gut) → First-pass Metabolism → Unchanged Drug → Systemic Circulation = **BIOAVAILABILITY (F)**

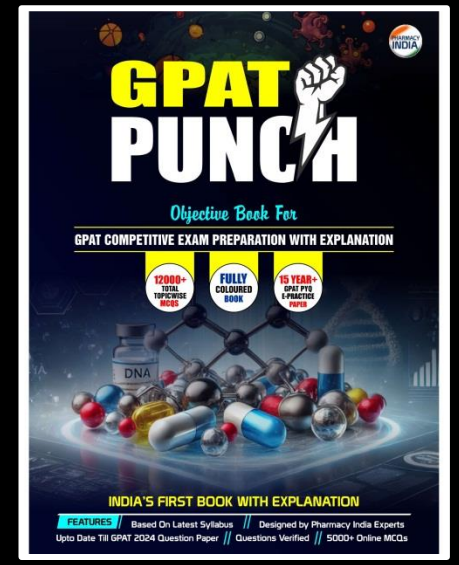
27. **Bioavailability of a drug depends upon:**

(a) First-pass metabolism

(b) Second-pass metabolism

(c) Volume of distribution

(d) Excretion



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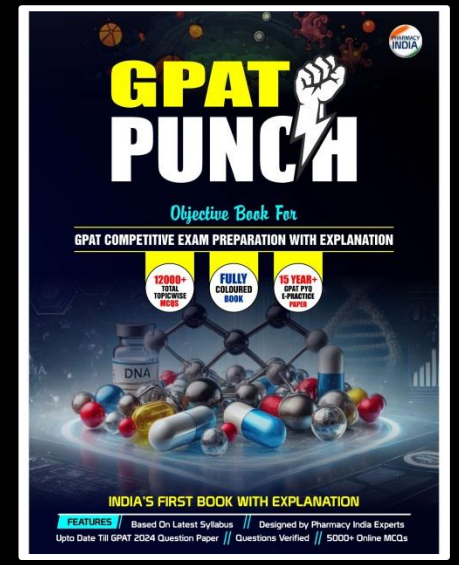


Determinants of Bioavailability

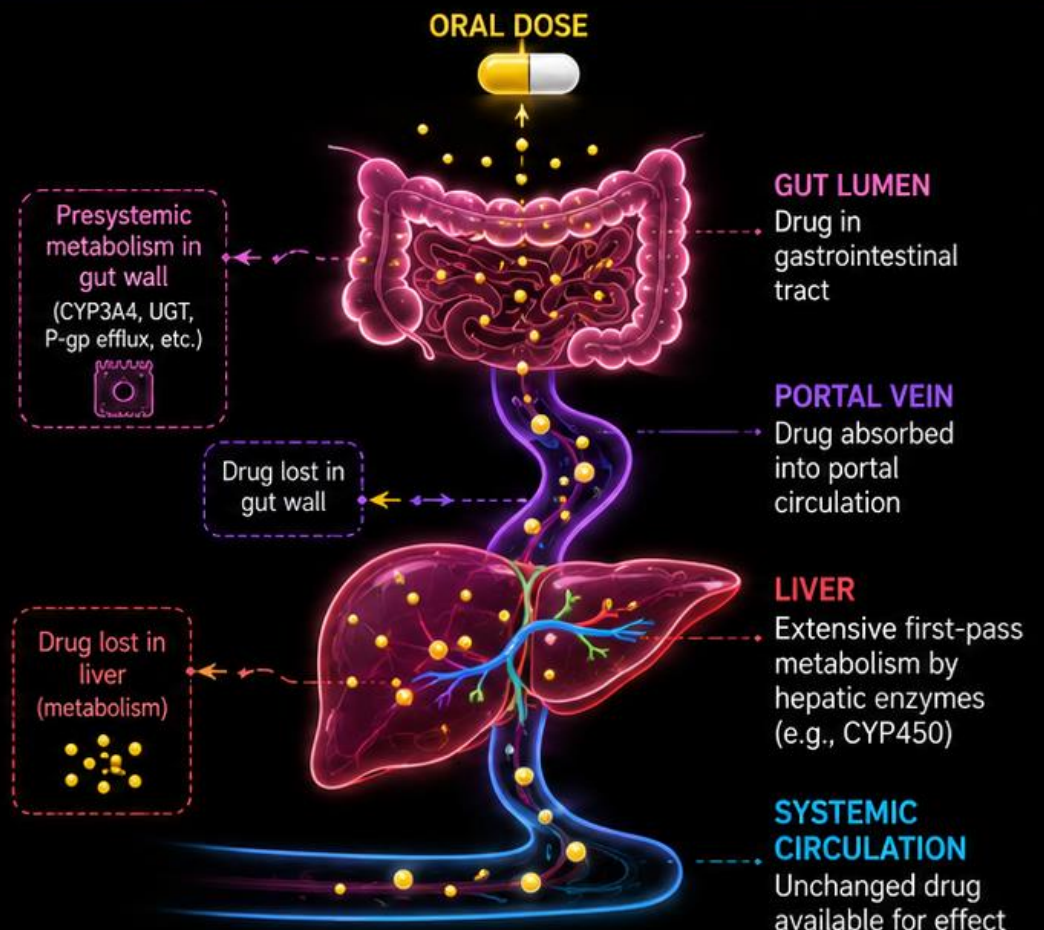
★ Extent & rate at which the **unchanged drug** reaches **systemic circulation** to produce its effect ★

First-pass metabolism is a major determinant of oral bioavailability.

Drug may be metabolized **in the gut wall and liver** before reaching **systemic circulation.**

Greater first-pass effect leads to **lower bioavailability.**

This may require **higher oral doses or non-oral routes.**



FACTORS INCREASING FIRST-PASS EFFECT

- High hepatic extraction (high E_h)
- High lipophilicity
- Extensive metabolism (CYP450, UGT, etc.)
- High plasma protein binding
- Efflux by P-glycoprotein

EXAMPLES

HIGH FIRST-PASS	LOW FIRST-PASS
• Propranolol	• Atenolol
• Lidocaine	• Metoprolol
• Morphine	• Warfarin
• Verapamil	• Diazepam
• Nitroglycerin	• Digoxin

KEY POINT | Oral dose → Absorption → Gut wall metabolism (loss) → Portal vein → Hepatic metabolism (loss) → Systemic circulation (unmetabolized drug)

Goal: Maximize unmetabolized drug in systemic circulation

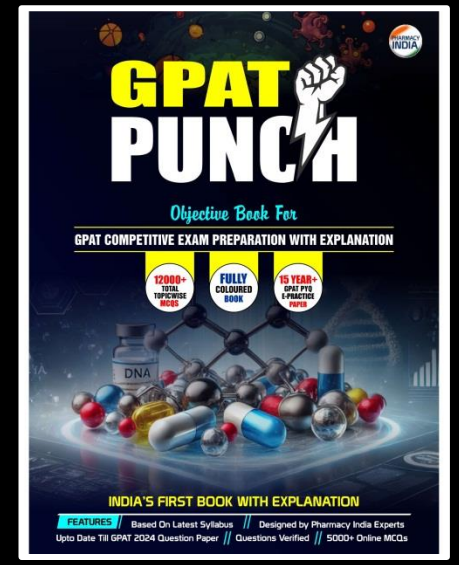
28. **Drug having highest first-pass metabolism among the following is:**

(a) Theophylline

(b) Aspirin

(c) Tolbutamide

(d) Lidocaine



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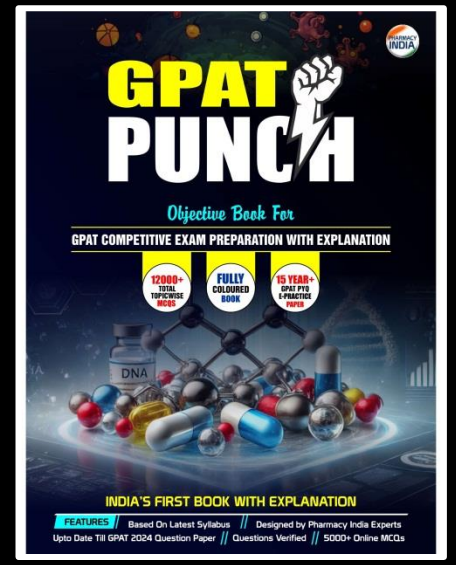


Lidocaine and First-Pass Metabolism

High First-Pass Drug → Low Oral Bioavailability → Prefer IV or Local Use

EXTENSIVE FIRST-PASS METABOLISM

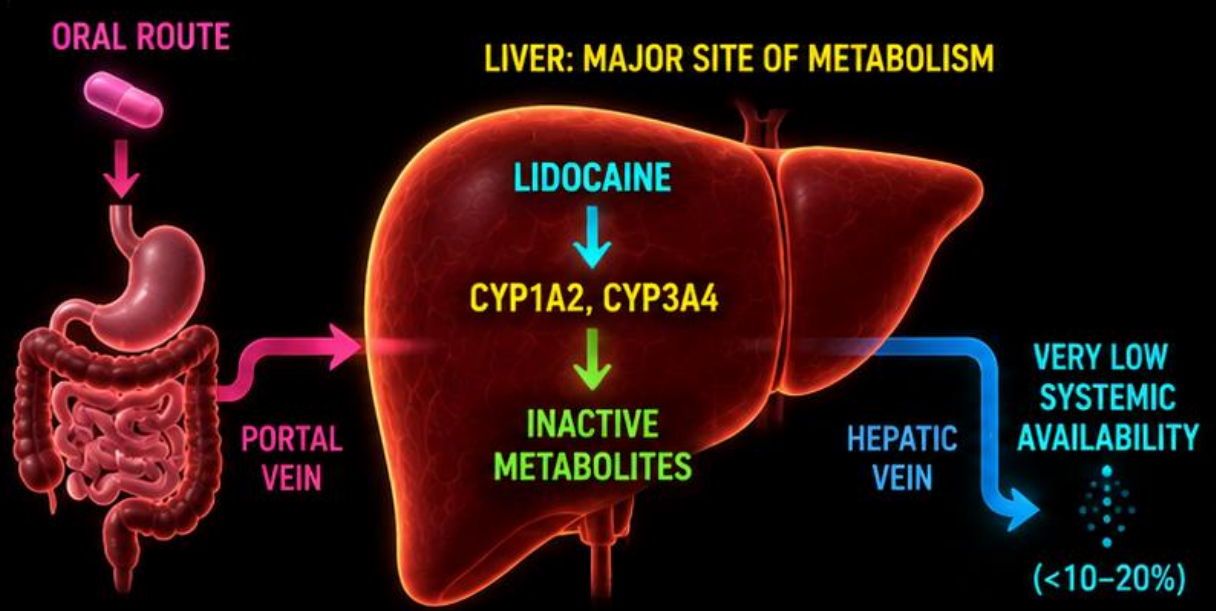
Lidocaine undergoes extensive first-pass hepatic metabolism (~70–90%).

LOW ORAL BIOAVAILABILITY

Oral use gives very low systemic availability (<10–20%).

CLINICAL IMPLICATION

Therefore it is used mainly by IV route or as a local anesthetic.



AMONG COMMON EXAMPLES, LIDOCAINE IS A CLASSIC HIGH FIRST-PASS DRUG.

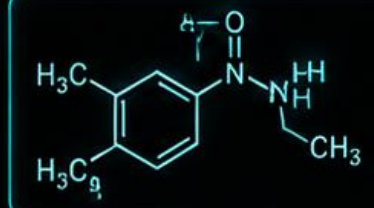
PREFERRED ROUTES OF USE

IV ROUTE

- ✓ Bypasses hepatic first-pass metabolism
- ✓ Rapid onset
- ✓ Higher & predictable bioavailability

LOCAL ANESTHETIC

- ✓ Infiltration / Nerve block
- ✓ Topical use
- ✓ Direct local action with minimal systemic exposure



LIDOCAINE

- Amide local anesthetic
- Antiarrhythmic (Class IB)
- Formula: $C_{14}H_{22}N_2O$

KEY TAKEAWAY

Lidocaine → high first-pass extraction → Oral bioavailability very low (<10–20%) → Use IV route or local anesthetic → Effective, safe, and reliable

EXAM PEARL

- High first-pass → low oral bioavailability.
- Think IV or Local!

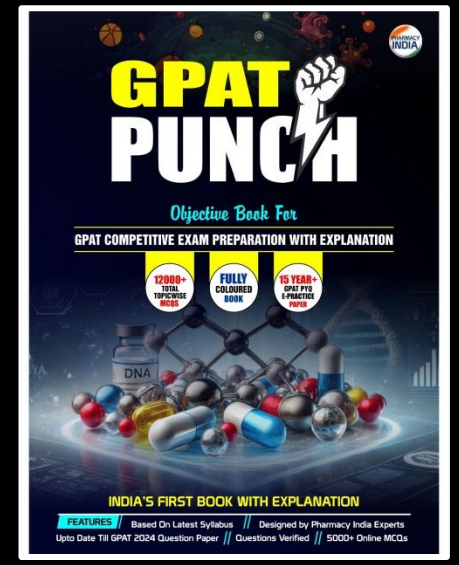
29. **In a plasma concentration-time curve for a drug following first-order kinetics, absorption rate constant is calculated based on:**

(a) t½

(b) Vd

(c) Css

(d) Clearance



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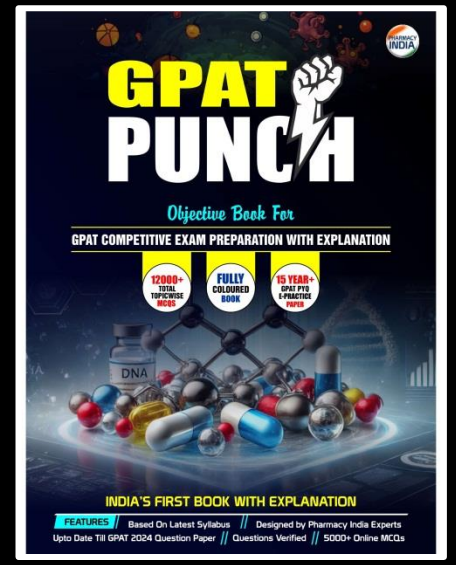


Absorption Rate Constant (k_a)

Quantifies the **RATE** of drug **ABSORPTION**

WHAT IS k_a?

First-order absorption rate constant.
Unit: $time^{-1}$ (e.g., h^{-1})

ABSORPTION HALF-LIFE

Time required for the amount of drug left to be absorbed to decrease by 50%.

INTERPRETATION

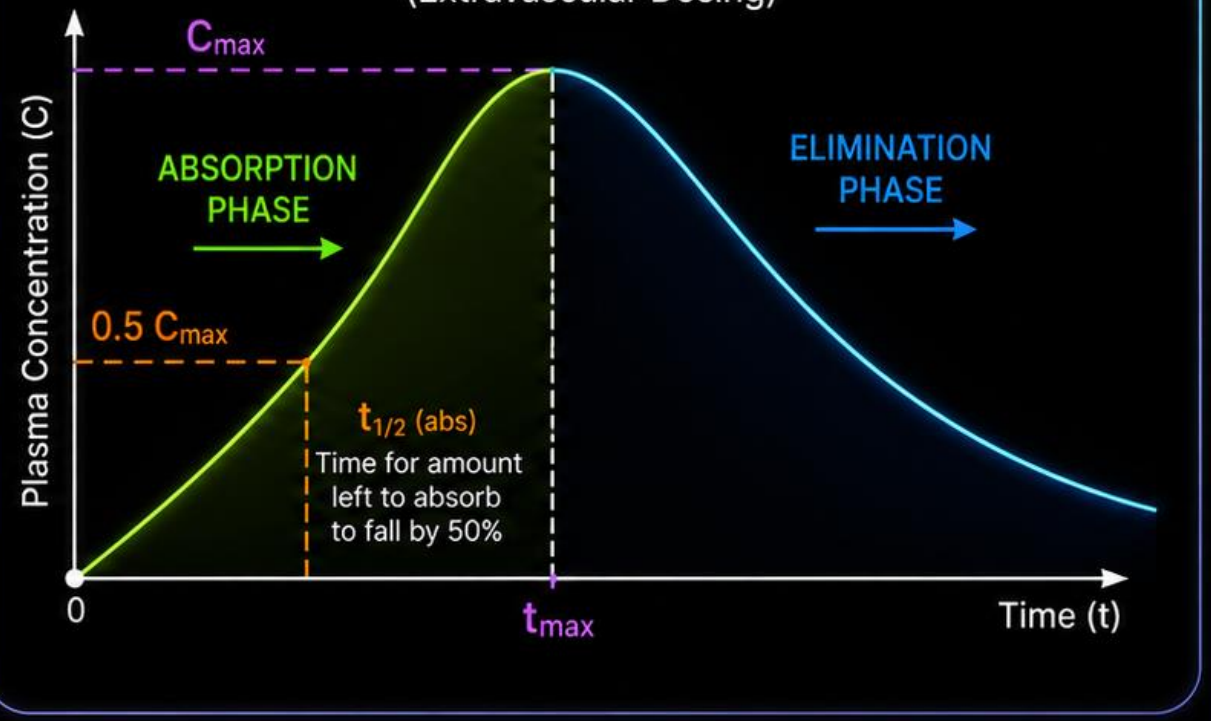
Shorter $t_{1/2}$ → Larger k_a → Faster absorption

Longer $t_{1/2}$ → Smaller k_a → Slower absorption

IMPORTANCE

- ✓ Determines how quickly a drug reaches systemic circulation.
- ✓ Influences onset of action and peak concentration (t_{max}, C_{max}).
- ✓ Critical in dosage form design and bioequivalence studies.

Plasma Concentration–Time Curve (Extravascular Dosing)



FORMULA

For first-order absorption, k_a is related to absorption half-life ($t_{1/2}$):

$$k_a = \frac{0.693}{t_{1/2(abs)}}$$

k_a unit: $time^{-1}$ (e.g., h^{-1})

KEY POINT

Shorter absorption half-life means faster absorption
Larger k_a indicates quicker entry into systemic circulation.

DERIVED FROM DATA

k_a is estimated by fitting plasma concentration–time data to a pharmacokinetic model (e.g., one-compartment model with first-order absorption).

REMEMBER

k_a describes ABSORPTION rate, not the extent (extent is described by bioavailability, F).

FACTORS AFFECTING k_a

- Dosage form
- Solubility & dissolution rate
- GI motility & gastric emptying
- Particle size & formulation
- Blood flow to absorption site

☆ High k_a → Rapid absorption → Early t_{max} | Low k_a → Slow absorption → Delayed t_{max} | Goal: Optimal k_a for desired onset and duration

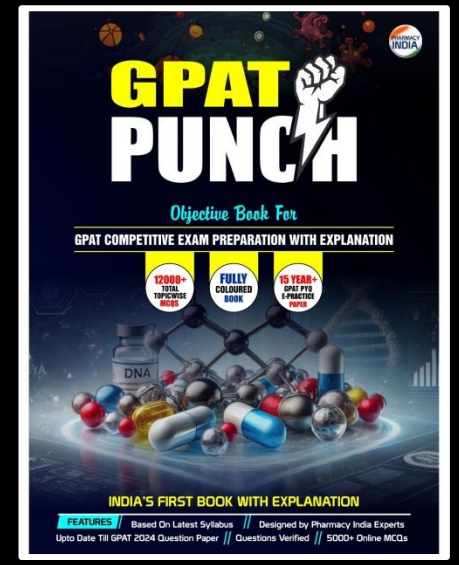
30. **The main purpose of titrating a drug dose is:**

(a) To get maximum benefit with minimum adverse effects

(b) To increase drug concentration rapidly without monitoring

(c) To avoid therapeutic effect

(d) To increase the cost of therapy



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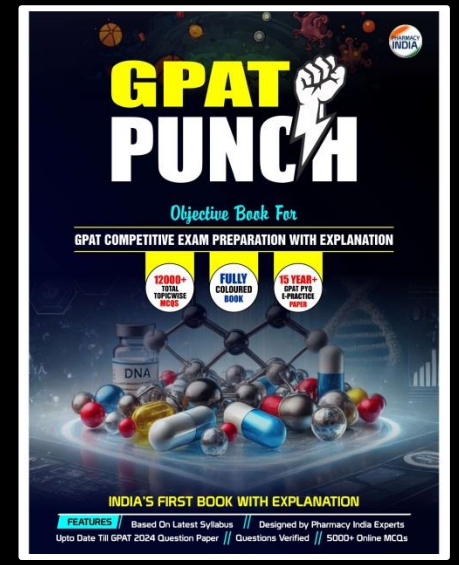


Dose Titration

Adjust the dose. Optimize the response. Protect the patient.

WHAT IS DOSE TITRATION?

Dose titration means adjusting the dose **stepwise** according to **patient response**.

MAIN AIM

Achieve **maximum therapeutic benefit** with **minimum adverse effects.**

INDIVIDUALIZED THERAPY

It helps **individualize** therapy according to age, weight, comorbidities, and patient response.

NARROW THERAPEUTIC WINDOW

Useful when patient response **varies** or the therapeutic window is **narrow**.

BALANCE IS THE GOAL

Maximize benefit while minimizing harm

HOW TO TITRATE?

1. **START LOW** — Begin with a low dose.
2. **ASSESS RESPONSE** — Evaluate efficacy & adverse effects.
3. **ADJUST DOSE** — Increase or decrease the dose stepwise.
4. **REASSESS** — Repeat until optimal response is achieved.

PATIENT MONITORING

- ✓ Monitor efficacy
- ✓ Watch for adverse effects
- ✓ Check vital signs & labs
- ✓ Ensure adherence
- ✓ Document & follow up

EXAMPLES OF DRUGS WHERE TITRATION IS COMMON

- **ANTIHYPERTENSIVES** — e.g., ACE inhibitors, Beta blockers
- **ANTIEPILEPTICS** — e.g., Phenytoin, Valproate
- **ANTIDEPRESSANTS** — e.g., SSRIs, TCAs
- **ASTHMA THERAPY** — e.g., Inhaled corticosteroids
- **ANTICOAGULANTS** — e.g., Warfarin (target INR)
- **ANTIDIABETICS** — e.g., Insulin

KEY TAKEAWAY

Right dose. Right patient. Right outcome.

Titrate today, treat better tomorrow.

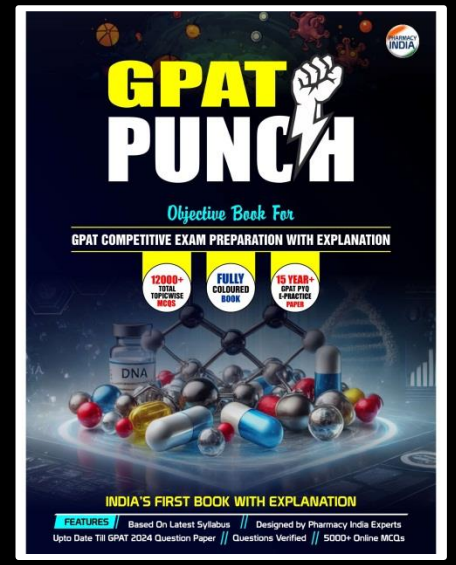
31. Which of the following drugs commonly requires therapeutic drug monitoring?

(a) Paracetamol

(b) Phenytoin

(c) Omeprazole

(d) Cetirizine



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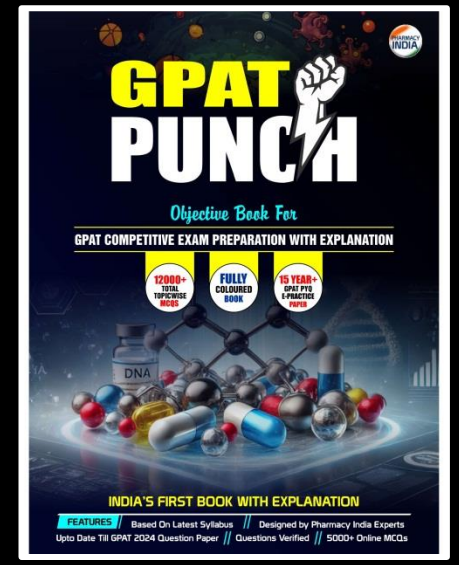


THERAPEUTIC DRUG MONITORING

PHENYTOIN COMMONLY REQUIRES THERAPEUTIC DRUG MONITORING

NARROW THERAPEUTIC INDEX
Small differences between therapeutic and toxic levels.

SATURABLE (NON-LINEAR) METABOLISM
Metabolized by CYP2C9/2C19.
Enzyme saturation → disproportionate rise in plasma levels.

SMALL DOSE CHANGES, BIG IMPACT
Minor dose increases may cause marked increase in plasma concentration.

MONITOR TO STAY IN RANGE
Aim for seizure control with minimal adverse effects.

PREVENT TOXICITY, IMPROVE OUTCOMES
Maintain efficacy, avoid CNS toxicity and serious adverse effects.

PHENYTOIN

Antiepileptic for seizure control

BLOOD SAMPLE

Measure trough plasma level

PLASMA LEVEL

Quantify phenytoin concentration

THERAPEUTIC RANGE

TOXIC
> 20 mcg/mL

THERAPEUTIC
10 – 20 mcg/mL

SUBTHERAPEUTIC
< 10 mcg/mL

Adjust dose to keep within range

Therapeutic levels maintain seizure control with minimal adverse effects.

High levels → CNS toxicity
- Nystagmus
- Ataxia
- Diplopia
- Drowsiness, confusion

KEY NOTE: Phenytoin's narrow therapeutic index and non-linear metabolism make **THERAPEUTIC DRUG MONITORING ESSENTIAL** for safe and effective therapy.

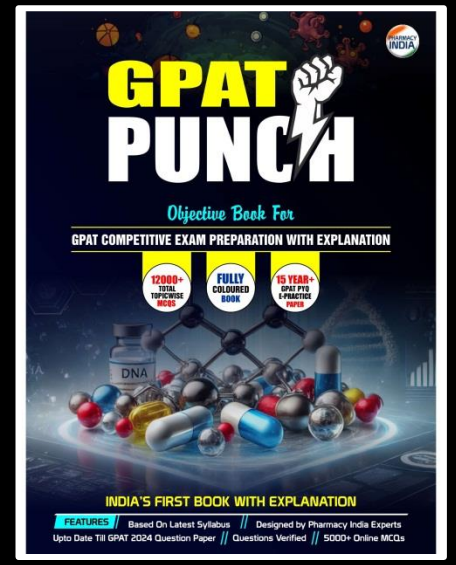
32. Which fixed-dose combination shows synergistic antibacterial action?

(a) Amlodipine + Atenolol

(b) Sulfamethoxazole + Trimethoprim

(c) Paracetamol + Caffeine

(d) Amoxicillin + Diclofenac



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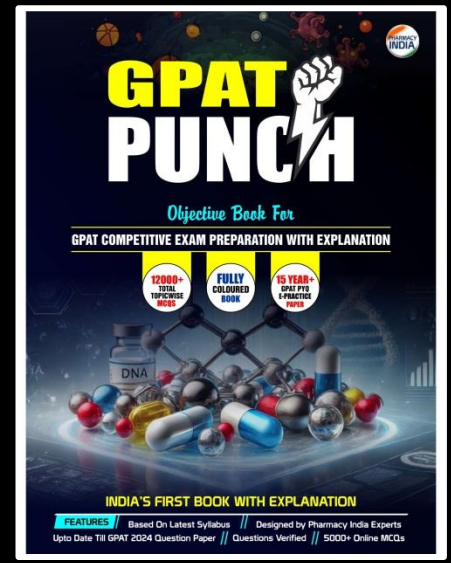

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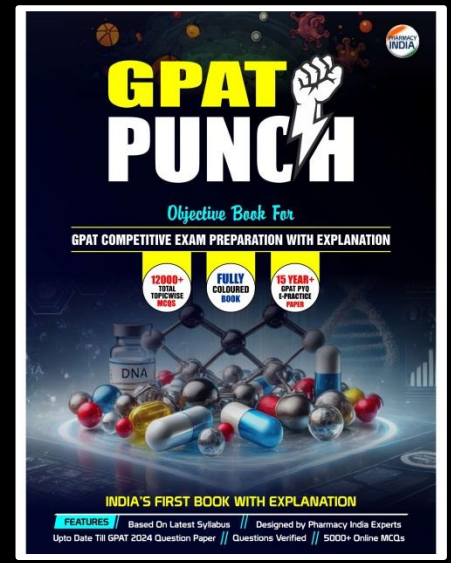


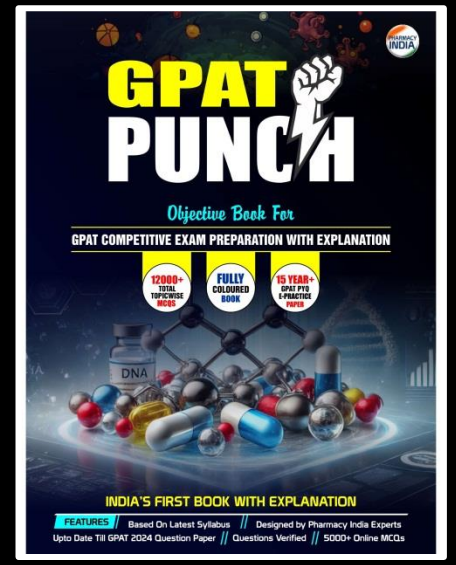
33. Combination therapy in tuberculosis and malaria is mainly used to:

(a) Increase drug cost

(b) Reduce patient compliance

(c) Prevent resistance and improve efficacy

(d) Avoid pharmacological action



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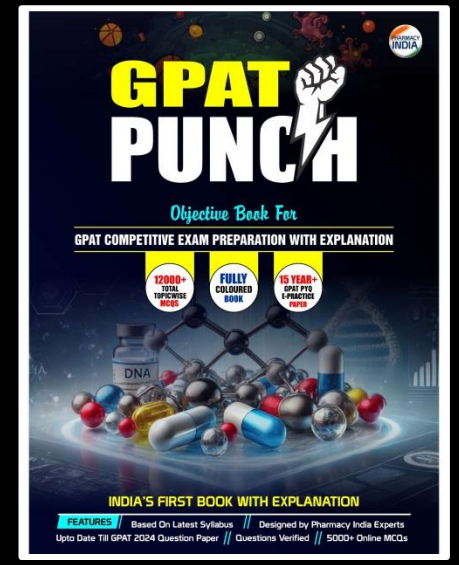


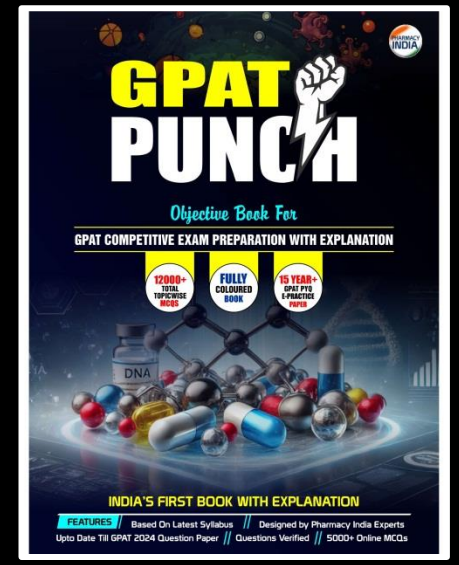
34. **The primary goal of rational prescribing is:**

(a) To prescribe maximum number of drugs

(b) To provide appropriate therapy with maximum benefit and minimum risk

(c) To prescribe only costly medicines

(d) To avoid patient counselling



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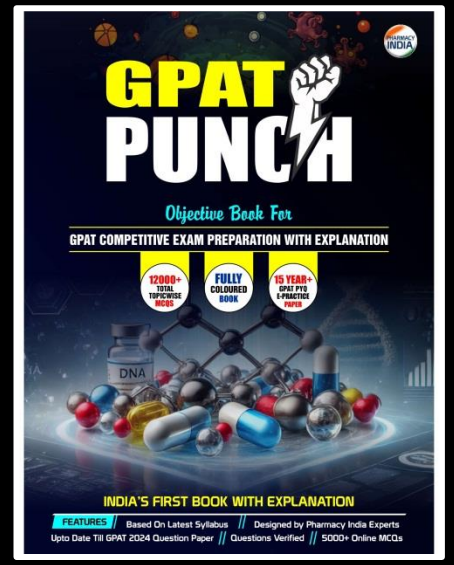


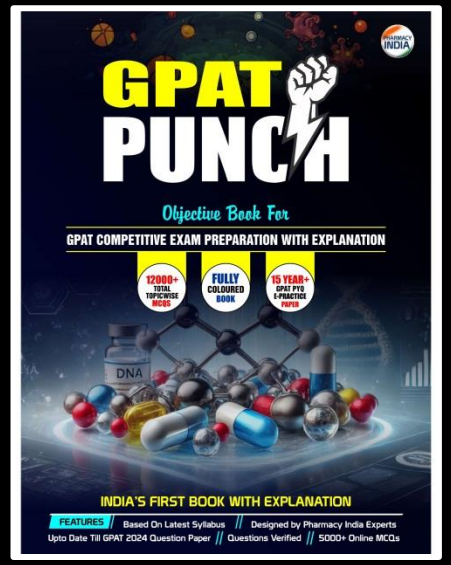
35. **Evidence-based medicine means:**

(a) Use of medicines only on the basis of personal experience

(b) Systematic use of best clinical research evidence in patient care

(c) Avoiding clinical trials

(d) Giving the same medicine to all patients



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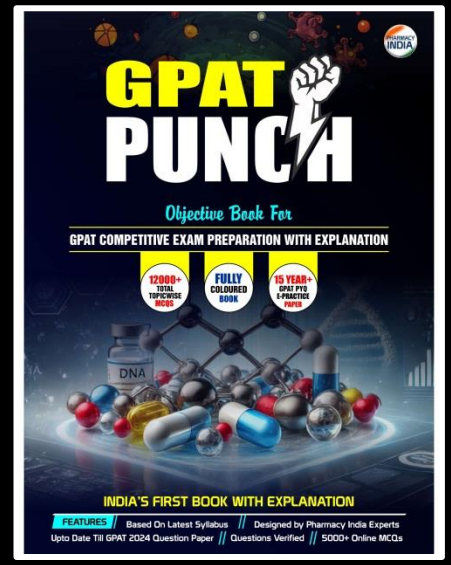


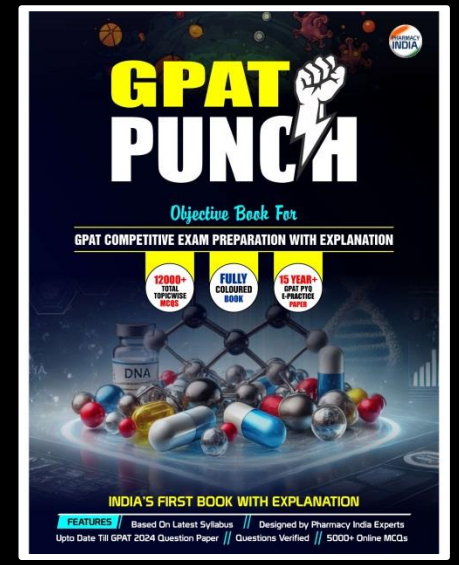
36. **A drug having a narrow therapeutic index generally requires:**

(a) No monitoring

(b) Therapeutic drug monitoring

(c) Only single dose therapy

(d) Avoidance of all laboratory tests



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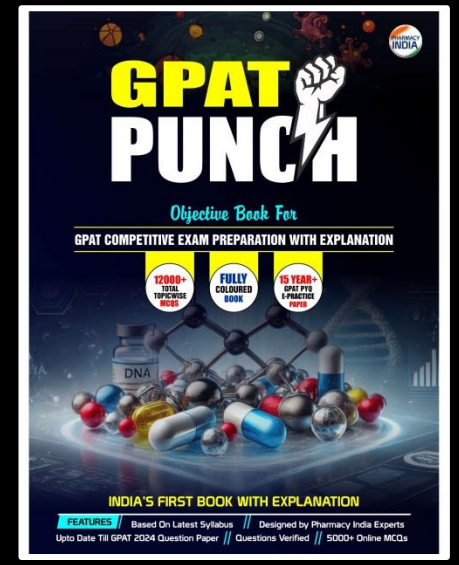


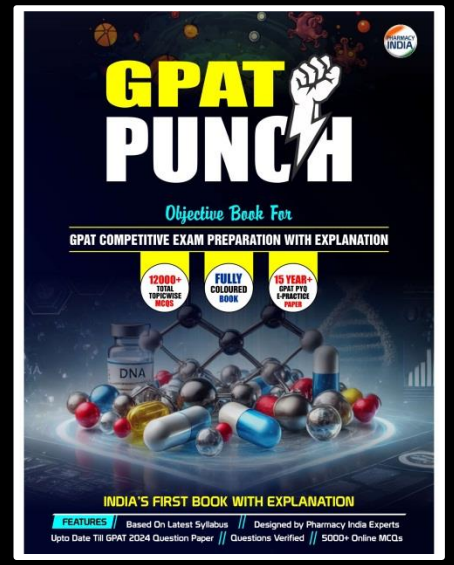
37. **Which study design is best suited to compare a new treatment with standard treatment under controlled conditions?**

(a) Case report

(b) Randomized controlled trial

(c) Cross-sectional survey

(d) Ecological study



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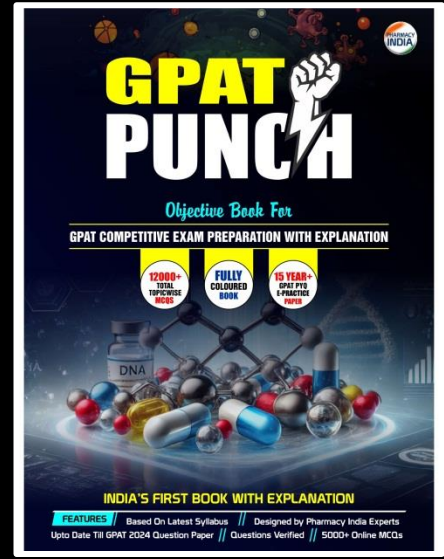


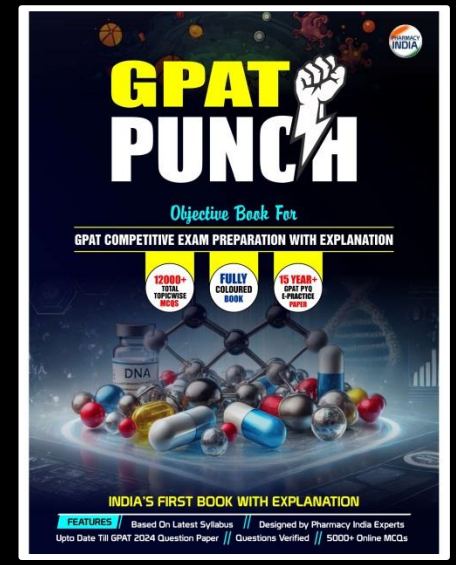
38. **Randomization in clinical trials is mainly done to:**

(a) Increase selection bias

(b) Reduce selection bias and balance groups

(c) Avoid informed consent

(d) Replace statistical analysis



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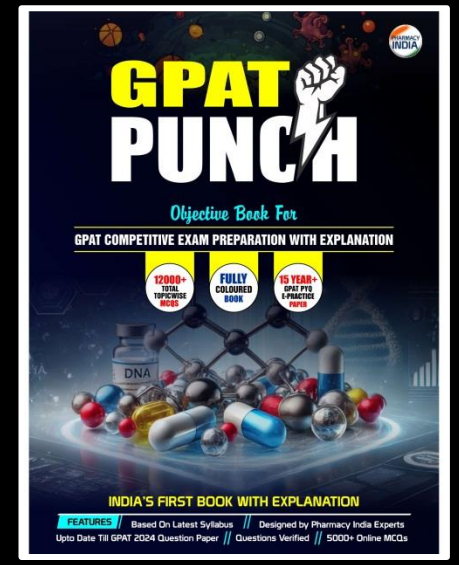

39. **Blinding in clinical trials is used to:**

(a) Increase observer bias

(b) Reduce subject and observer bias

(c) Avoid ethics committee approval

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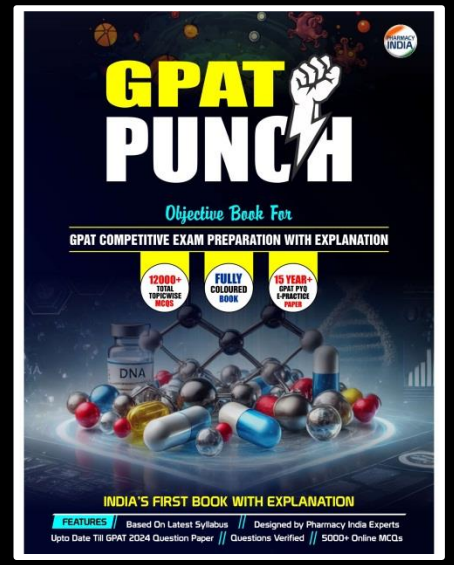

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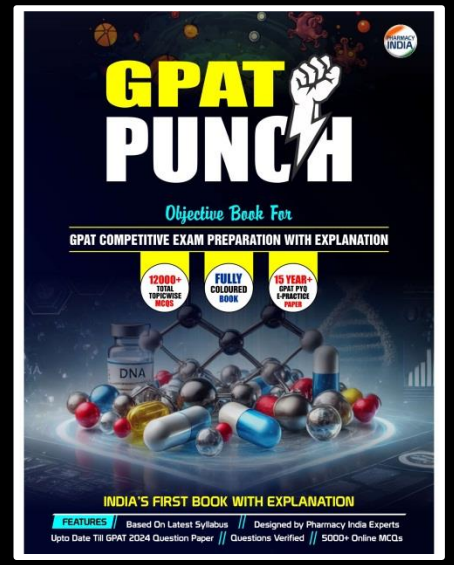


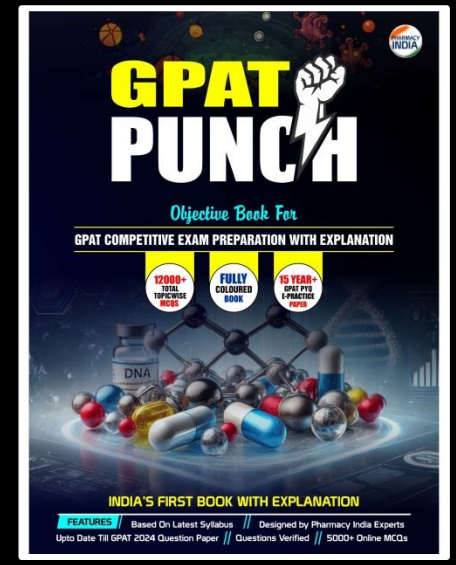
40. **A double-blind clinical trial means:**

(a) Only patient knows treatment allocation

(b) Only investigator knows treatment allocation

(c) Both patient and investigator are unaware of treatment allocation

(d) Neither drug nor placebo is used



40. **A double-blind clinical trial means:**

(a) Only patient knows treatment allocation

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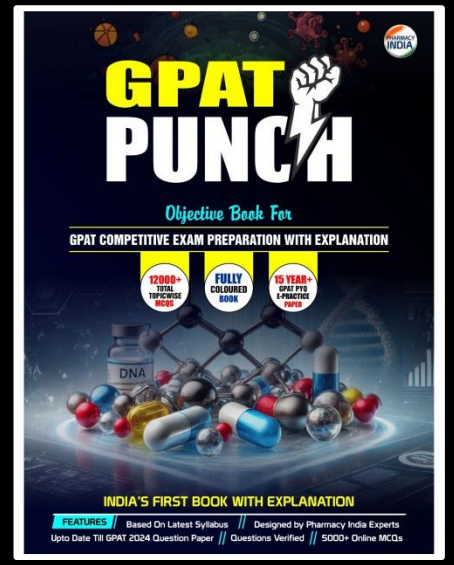
41. **A placebo-controlled trial includes:**

(a) Only active drug group

(b) Only animal subjects

(c) A pharmacologically inert comparator group

(d) No comparator group



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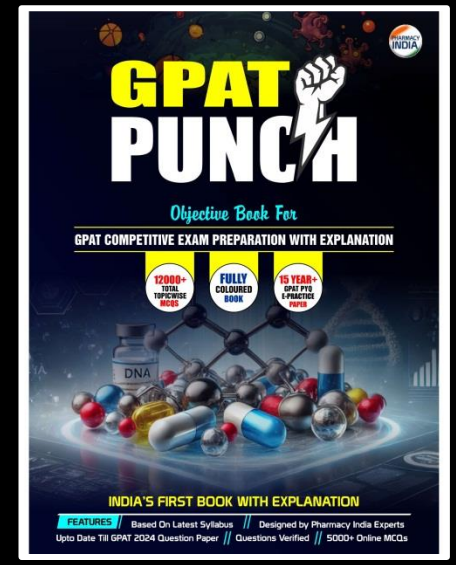


PLACEBO-CONTROLLED TRIAL

The Gold Standard for Evaluating Treatment Efficacy & Safety

1. WHAT IS IT?

A clinical trial in which one group receives the active treatment and the other receives a placebo for comparison.

2. PLACEBO DEFINED

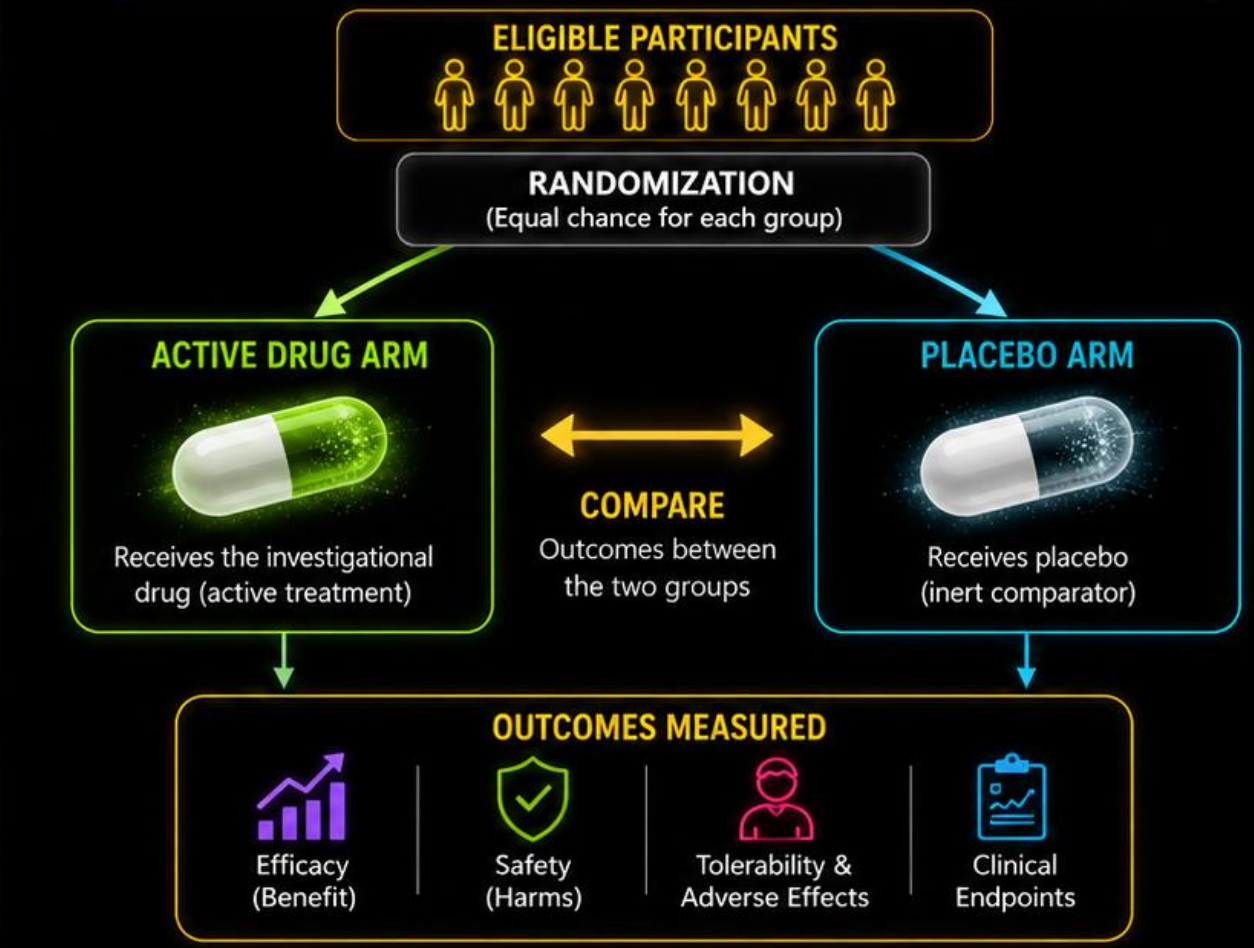
A pharmacologically inert substance (e.g., sugar pill, saline) with no specific therapeutic effect.

3. PURPOSE

- Compare true drug effect vs. no active treatment effect
- Determine efficacy
- Assess safety & adverse effects more accurately

4. REDUCES BIAS

Controls for expectation, belief, and natural course of disease (placebo response).



5. USUALLY COMBINED WITH

- Blinding (single, double, or triple) to prevent bias
- Randomization to balance known & unknown confounders

6. BENEFITS

- More accurate estimate of true treatment effect
- Improves internal validity
- Helps detect both benefits and harms

7. ETHICAL USE

Used when no proven standard therapy exists, or when withholding treatment poses minimal risk and is ethically justified.

8. LIMITATIONS

- May be unethical in life-threatening conditions
- Placebo response can vary across populations

KEY POINT

The placebo group is the **inert comparator group**.
It shows what happens with **NO** active treatment effect, helping reveal the **TRUE** effect of the investigational drug.

Placebo-controlled trials are the cornerstone of evidence-based medicine.

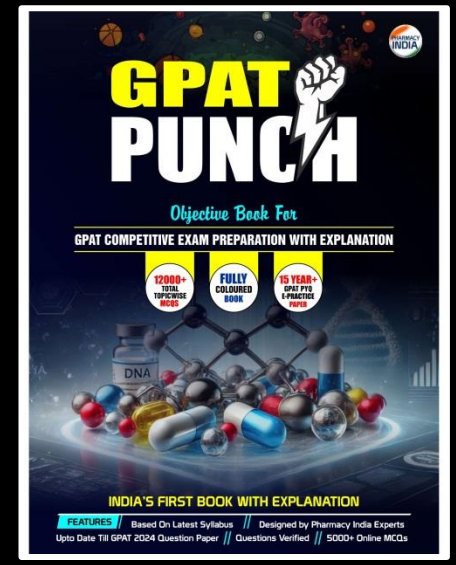
42. **In drug development, preclinical studies are mainly performed in:**

(a) Healthy volunteers

(b) Patients with disease

(c) Animals and in vitro systems

(d) Post-marketing population



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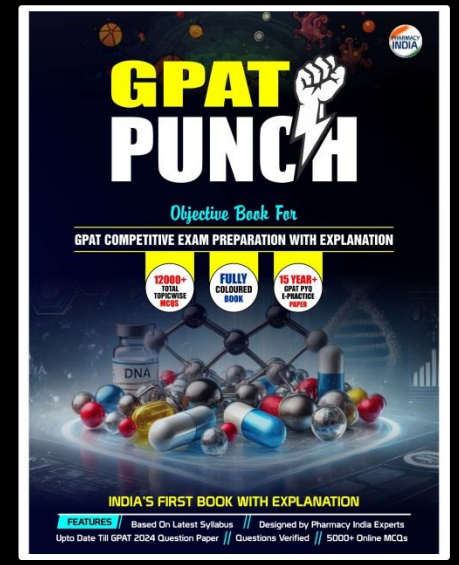


PRECLINICAL STUDIES

THE FOUNDATION BEFORE HUMAN TRIALS

DONE BEFORE HUMAN TRIALS

Conducted after in vitro and formulation studies, but before clinical trials in humans.

PERFORMED IN ANIMALS & IN VITRO SYSTEMS

Includes animal models and cell/tissue-based in vitro experiments.

EVALUATES KEY ASPECTS

- Pharmacological activity (efficacy)
- PK clues (ADME)
- Preliminary safety (toxicity)

IN VITRO SYSTEMS • ANIMAL STUDIES

HELPS IDENTIFY

- Suitable dose range (min–max)
- Therapeutic window
- Major target organ toxicities

IDENTIFIES MAJOR RISKS EARLY

Detects serious adverse effects and potential safety liabilities.

PROVIDES EVIDENCE TO PROCEED

If benefits outweigh risks and data are acceptable, the drug candidate moves toward human testing.

KEY TAKEAWAY

Preclinical work is mainly in **ANIMALS** and **IN VITRO SYSTEMS**, **NOT** in patients or healthy volunteers.

PHARMACOLOGY | TOXICOLOGY | PK/ADME | EFFICACY | SAFETY | GO/NO-GO DECISION

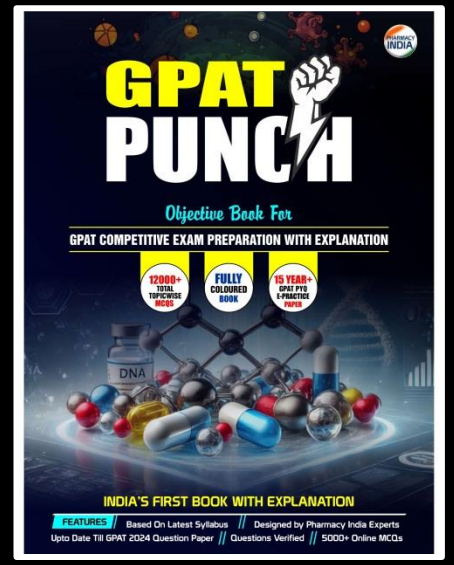
43. **The main purpose of preclinical toxicity studies is to:**

(a) Determine market price of drug

(b) Identify safety profile before human trials

(c) Replace clinical trials

(d) Study patient compliance only



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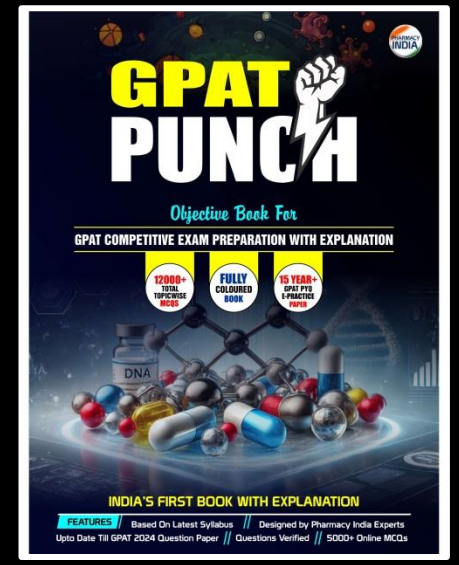


PRECLINICAL TOXICITY STUDIES

Evaluate safety before first-in-human use

1. PURPOSE

Identify the safety profile of a new chemical entity before human trials.

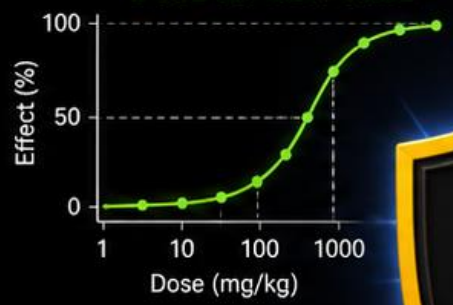
2. DETECTS TOXIC EFFECTS

Detects harmful effects and identifies target organ(s) of toxicity.

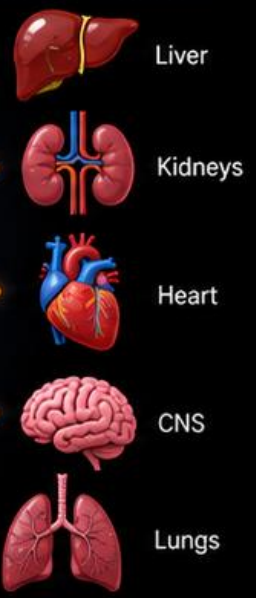
3. TYPES OF STUDIES

- Acute (single dose)
- Subacute/Subchronic (14–90 days)
- Chronic (≥ 6 months)
- Reproductive & Developmental
- Genotoxicity (Mutagenicity)
- Carcinogenicity (as needed)

DOSE vs. RESPONSE



TARGET ORGANS



STUDY DESIGN

4. GUIDES CLINICAL TRIALS

Helps estimate safe starting dose, dose range, and monitoring plan.

5. PROTECTS HUMAN SAFETY

Prevents unsafe compounds from entering human studies.

6. DATA USED FOR DECISIONS

Results inform risk–benefit assessment and regulatory approval for clinical trials.

7. REGULATORY COMPLIANCE

Conducted per GLP guidelines and ICH (e.g., M3(R2)) requirements.

KEY POINT: The main goal of preclinical toxicity studies is **SAFETY PROFILING** BEFORE **FIRST-IN-HUMAN** USE.

Science for Safer Medicines | Ethical | Systematic | Data-Driven | Patient Safety First

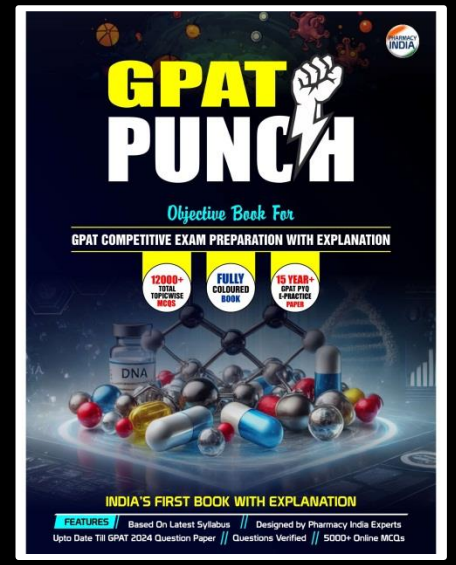
44. **Investigational New Drug application is generally submitted to obtain permission for:**

(a) Starting clinical trials in humans

(b) Selling the generic drug

(c) Advertising the drug

(d) Stopping post-marketing surveillance



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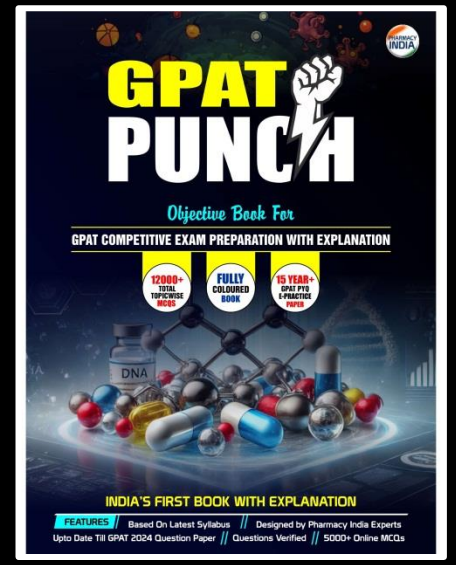


INVESTIGATIONAL NEW DRUG (IND) APPLICATION

1 SUBMITTED BEFORE HUMAN TRIALS
Must be submitted to the regulatory authority before starting clinical trials in humans.

2 CONTAINS PRECLINICAL SAFETY DATA
Includes results of pharmacology, toxicology, and other studies supporting initial human testing.

3 INCLUDES MANUFACTURING & QUALITY INFORMATION
Provides details on drug substance and product, manufacturing process, controls, and stability.

4 PROPOSED CLINICAL PROTOCOL & INVESTIGATOR INFO
Describes study design, dose, subject safety measures, and investigator qualifications.

5 REGULATORY AUTHORITY REVIEWS
Authority reviews the IND to ensure subject safety and data adequacy before allowing human testing.

PRECLINICAL STAGE
Laboratory / Animal Studies

IND APPLICATION
- Preclinical Data
- Manufacturing Information
- Clinical Protocol
- Investigator Information

HUMAN CLINICAL TRIAL
After Regulatory Approval

WHY IND IS IMPORTANT

PROTECTS HUMAN SUBJECTS
Ensures safety data is reviewed before trials.

ENSURES DATA INTEGRITY
Confirms scientific justification for trials.

STANDARDIZES QUALITY
Ensures the investigational drug is manufactured consistently and safely.

REGULATORY GATEWAY
Formal permission to begin human clinical trials.

KEY TAKEAWAY

IND = PERMISSION TO START HUMAN CLINICAL TRIALS

No clinical trial in humans may begin until the IND is reviewed and there is no clinical hold by the regulatory authority.

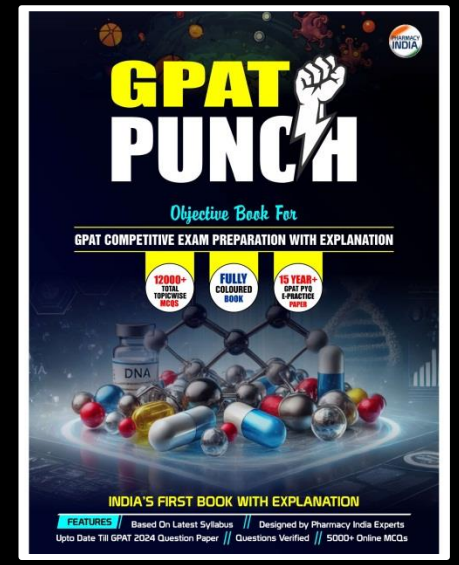
45. **New Chemical Entity means:**

(a) A drug already marketed for many years

(b) A completely new active substance not previously approved

(c) A new package design only

(d) A placebo formulation



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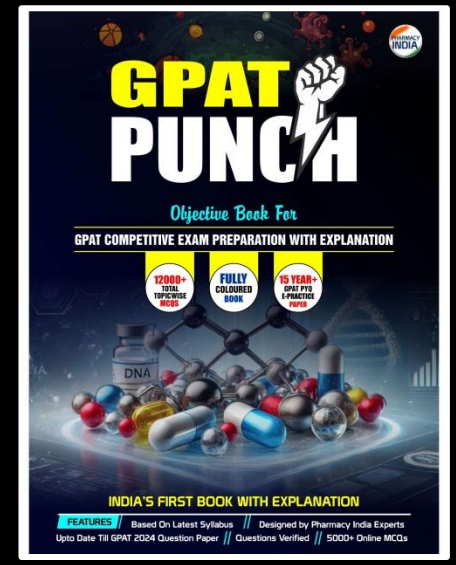


NEW CHEMICAL ENTITY (NCE)

A NOVEL ACTIVE SUBSTANCE WITH THERAPEUTIC POTENTIAL

1. COMPLETELY NEW

An NCE is a completely new active substance with a unique chemical structure.

2. NOT PREVIOUSLY APPROVED

It has not been previously approved anywhere in the world for marketing.

3. NOT A GENERIC OR FORMULATION CHANGE

Differs from a generic (same active ingredient) or a mere formulation/ package change.

4. REQUIRES FULL DEVELOPMENT PROGRAM

Must undergo a complete development pathway: preclinical and clinical evaluation for safety, efficacy and quality.

5. ORIGINAL DRUG DISCOVERY

Represents innovation and intellectual contribution in drug discovery research.

6. ELIGIBLE FOR PATENT PROTECTION

Usually eligible for patent protection, encouraging innovation.

KEY POINT: NCE MEANS A NEW ACTIVE SUBSTANCE, NOT JUST A NEW BRAND OR PACKAGE.

- ✓ Different active ingredient = NCE
- ✗ Same active ingredient = Not an NCE (Generic)
- ✗ New formulation/pack = Not an NCE

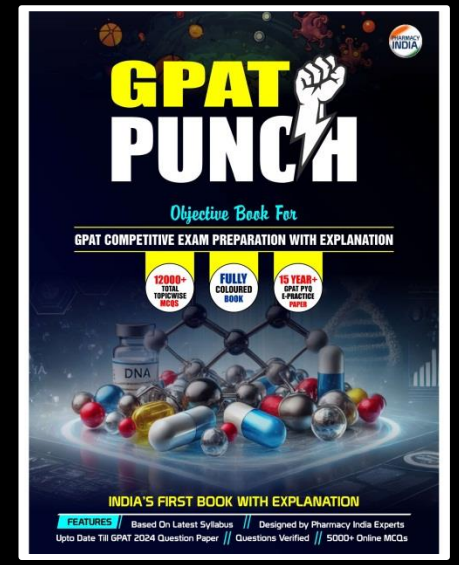
46. **Bioequivalence studies are mainly required for:**

(a) Approval of generic formulations

(b) Discovery of new receptors

(c) Animal toxicity testing

(d) Determining teratogenicity only



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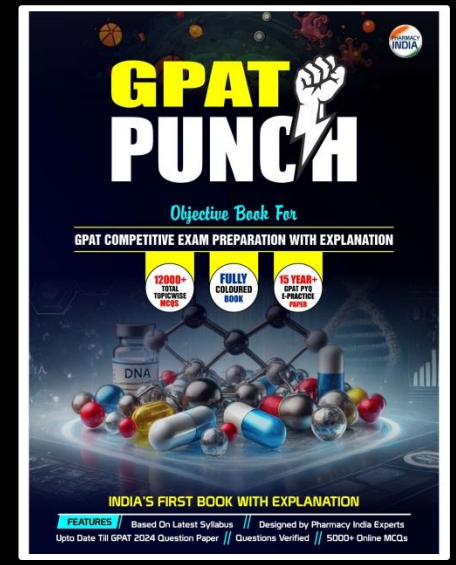


BIOEQUIVALENCE STUDIES

Ensuring Generic Medicines are as Safe, Effective, and Reliable as the Reference Product

REQUIRED FOR GENERIC APPROVAL
Bioequivalence studies are mainly required for approval of generic formulations.

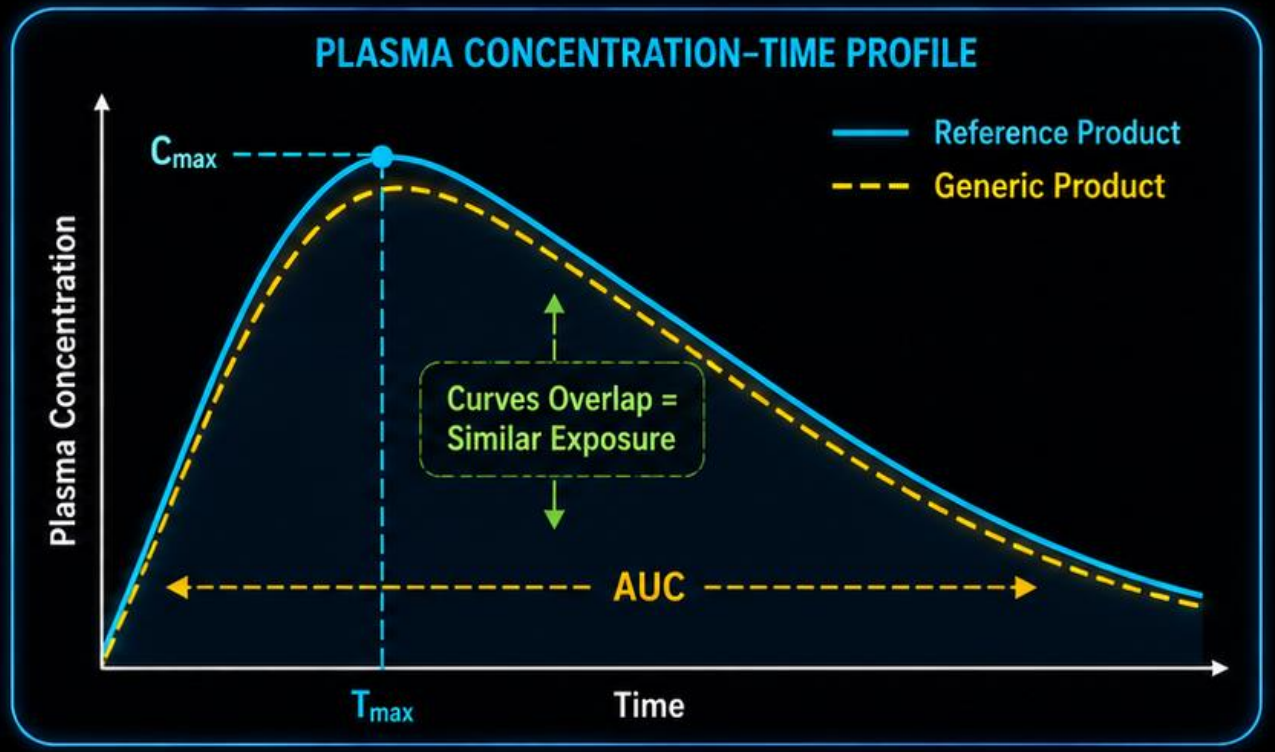
COMPARES RATE & EXTENT OF ABSORPTION
Compares the rate (speed) and extent (amount) of absorption between generic and reference products.

PK MEASURES USED
Common pharmacokinetic measures include C_{max}, T_{max}, and AUC.

THERAPEUTIC EQUIVALENCE
When bioavailability is similar, the generic is expected to have the same therapeutic effect and safety.

ENSURES SUBSTITUTABILITY
Helps ensure the generic product can be used in place of the reference product without loss of efficacy or safety.

PLASMA CONCENTRATION–TIME PROFILE



KEY PK PARAMETERS

C_{max}
Maximum observed plasma concentration

T_{max}
Time to reach C_{max}

AUC
Area Under the Curve (total drug exposure)

HOW IT'S DONE

In Vivo Studies
Usually conducted in healthy volunteers under controlled conditions.

Single-Dose or Multiple-Dose
Depends on the drug's characteristics.

Blood Sampling
Plasma samples collected at predefined time points.

PK Analysis
Calculate C_{max}, T_{max}, AUC and other parameters.

Statistical Comparison
90% Confidence Interval (CI) of Test/Reference for C_{max} and AUC should be within 80.00% – 125.00%.

KEY POINT
Generic approval commonly depends on demonstrating bioequivalence.

Goal: Same Active Ingredient • Same Strength • Same Dosage Form • Same Route of Administration • Same Therapeutic Effect

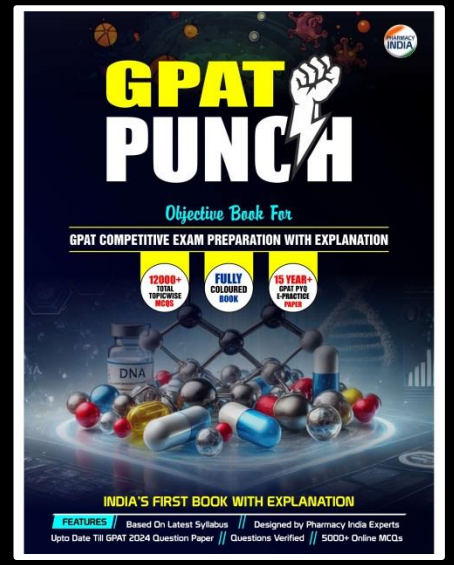
47. **A crossover clinical study means:**

(a) Each participant receives more than one treatment in sequence

(b) Only one treatment is tested without comparison

(c) Trial is conducted only after marketing

(d) Only animals are crossed between groups



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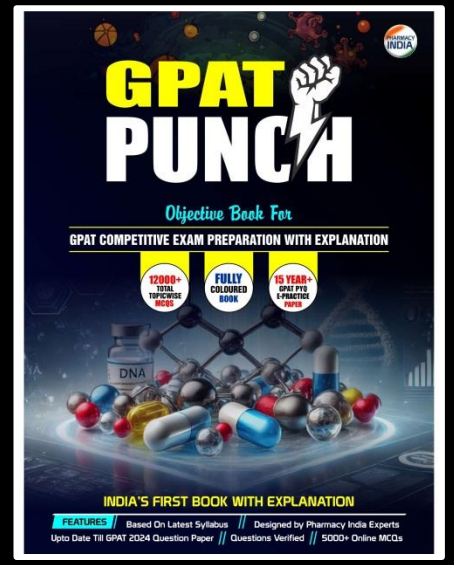


CROSSOVER STUDY

Each participant receives **more than one treatment** in sequence

DEFINITION
A study design in which participants receive multiple treatments in a predetermined sequence.

OWN CONTROL
Each participant serves as their own control.

REDUCES VARIABILITY
Reduces inter-subject variability and increases statistical power.

WHEN TO USE
Useful when the condition is stable and the treatment effect is reversible.

WASHOUT PERIOD
Usually separated by a washout period to prevent carryover effects.

KEY CONSIDERATIONS
- Randomize sequence (A→B or B→A)
- Ensure adequate washout
- Watch for period effects and carryover

KEY POINT: The defining feature of a crossover study is that the same participant receives multiple treatments.

HIGH EFFICIENCY
Requires fewer participants.

COST-EFFECTIVE
More information from the same sample size.

ETHICALLY USEFUL
All participants get active treatments.

BETTER CONTROL
Minimizes effect of confounders.

COMMON EXAMPLES
Pain studies, BP drugs, chronic stable conditions.

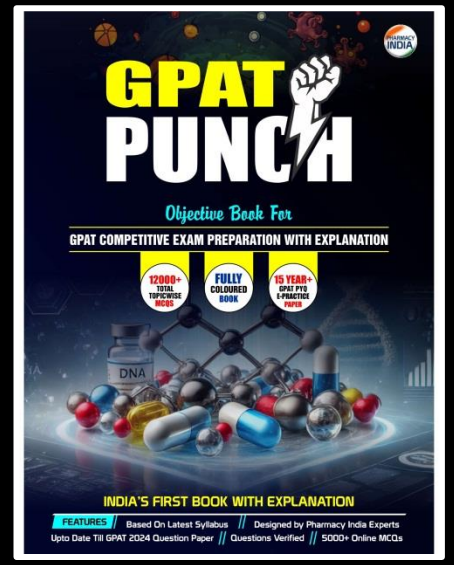
48. **A washout period in a crossover study is used to:**

(a) Increase carryover effect

(b) Eliminate effect of previous treatment before next treatment

(c) Avoid drug administration

(d) Stop randomization



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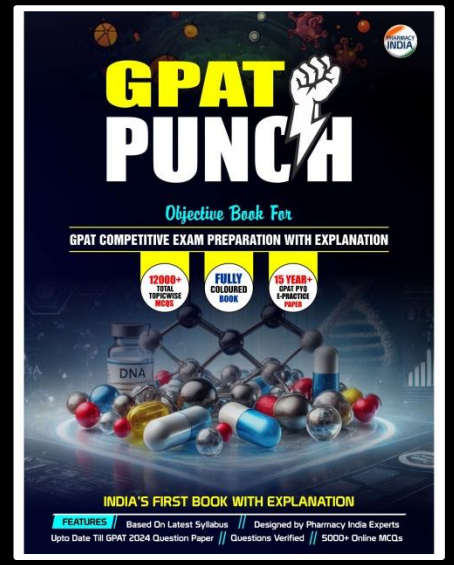


WASHOUT PERIOD

A gap between two treatment periods in a **crossover study** to eliminate **residual effects** of the first treatment before starting the next.

1. USED IN CROSSOVER STUDIES

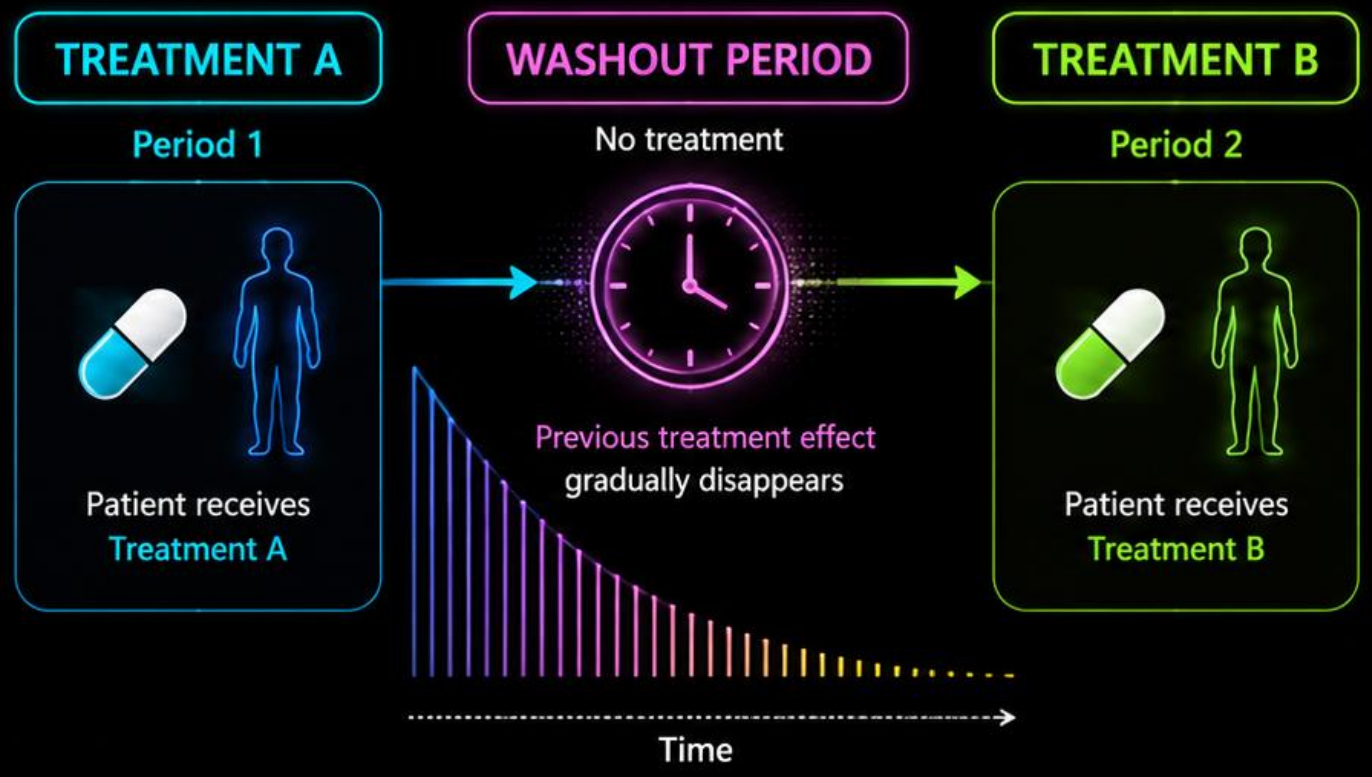
Participants receive multiple treatments in sequence.

2. ALLOWS EFFECT TO DISAPPEAR

Ensures the effect of the first treatment wears off before the next begins.

3. MINIMIZES CARRYOVER EFFECT

Prevents the previous treatment from influencing outcomes in the next period.



4. DURATION DEPENDS ON DRUG FACTORS

Based on drug half-life and pharmacodynamic effect.

5. IMPROVES VALIDITY OF COMPARISON

Provides a fair and unbiased comparison between treatments.

6. GUIDED BY SCIENCE

Use ≥ 4–5 half-lives or until the effect is clinically negligible.

KEY TAKEAWAY

Washout prevents the previous treatment from influencing the next one.
It ensures clean results and valid treatment comparisons.

Remember: Adequate washout = Reliable results | Inadequate washout = Risk of carryover bias

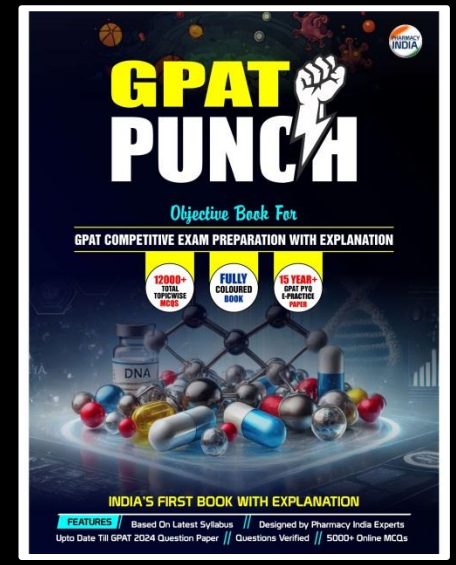
49. **Informed consent in clinical trial means:**

(a) Permission obtained without explaining risks

(b) Voluntary agreement after explaining study details, risks and benefits

(c) Approval only from investigator

(d) Consent taken only after completion of trial



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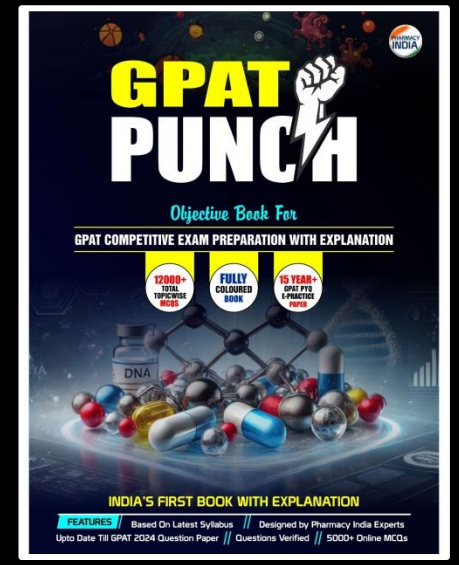


INFORMED CONSENT

Ethical • Respectful • Transparent • Participant-Centered

1 VOLUNTARY AGREEMENT

Participation is completely voluntary. You decide freely.

2 FULL INFORMATION

Provided after explaining the study purpose, procedures, risks, benefits, and alternatives.

3 ASK QUESTIONS

You must have the opportunity to ask questions and get clear answers.

RISKS
Understand possible harms

BENEFITS
Understand potential benefits

CONFIDENTIALITY
Your information is protected

VOLUNTARY PARTICIPATION
Your choice, your rights

4 DOCUMENTATION

Consent should be documented using a written form (or verbal consent where permitted).

5 RIGHT TO WITHDRAW

You can withdraw at any time without giving a reason and without penalty.

6 RESPECT & AUTONOMY

Your decision will be respected and will not affect your care or rights.

KEY POINT

Informed consent is **NOT** just a signature, it is an **INFORMED VOLUNTARY DECISION.**

FOUNDATION OF ETHICAL RESEARCH

Protects participants. Builds trust. Ensures integrity.

ETHICAL PRINCIPLES

Respect for persons • Beneficence • Non-maleficence • Justice

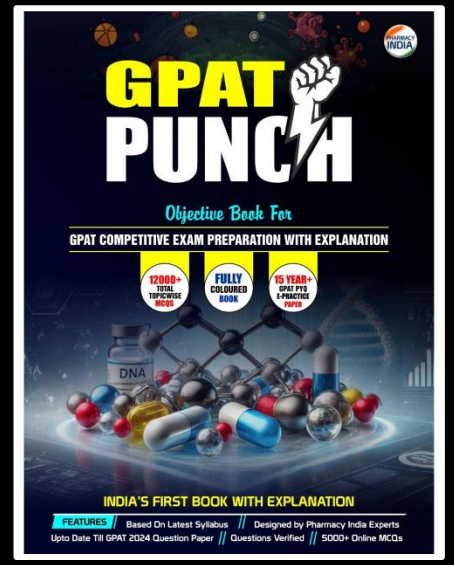
50. **Institutional Ethics Committee mainly ensures:**

(a) Marketing promotion of drug

(b) Protection of rights, safety and well-being of trial participants

(c) Increase in drug price

(d) Manufacturing of the study drug



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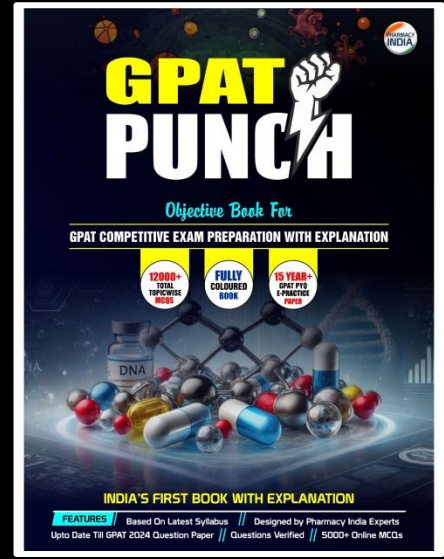

INSTITUTIONAL ETHICS COMMITTEE (IEC)

ETHICAL OVERSIGHT FOR ETHICAL RESEARCH

1. REVIEWS & APPROVES

- Reviews research protocols, documents and materials
- Approves only scientifically valid and ethically acceptable studies

2. PROTECTS PARTICIPANTS

- Protects the rights, safety, dignity and well-being of trial participants
- Ensures vulnerable groups are protected

3. EVALUATES RISK–BENEFIT & INFORMED CONSENT

CONSENT

- Assesses risk–benefit balance
- Ensures informed consent process is appropriate, clear and voluntary

4. MONITORS ETHICAL CONDUCT

- Monitors ongoing studies for safety and ethical conduct
- Reviews progress reports, SAEs and protocol deviations

5. TAKES NECESSARY ACTION

- Can recommend modifications, suspension or termination if risks outweigh benefits
- Ensures compliance with laws, guidelines and GCP

6. INDEPENDENT OVERSIGHT

- Operates independently of investigators and sponsors
- Essential before and during the entire trial

KEY TAKEAWAY

IEC PRIMARILY SAFEGUARDS TRIAL PARTICIPANTS

by ensuring ethical design, informed participation, risk minimization, and continuous oversight of clinical research.

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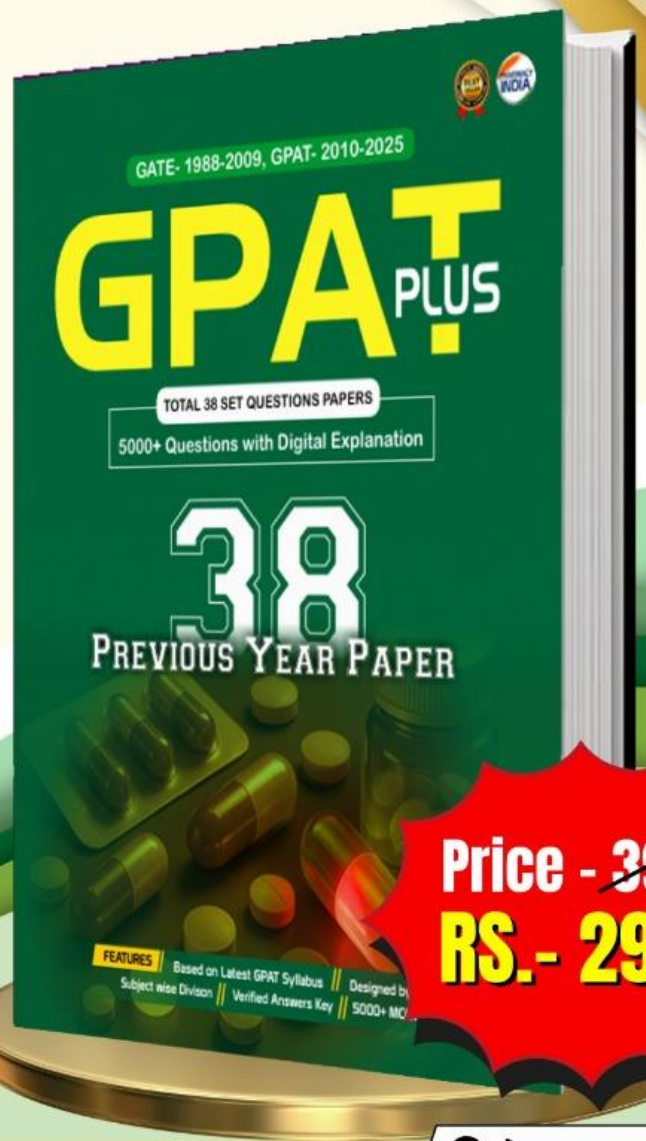

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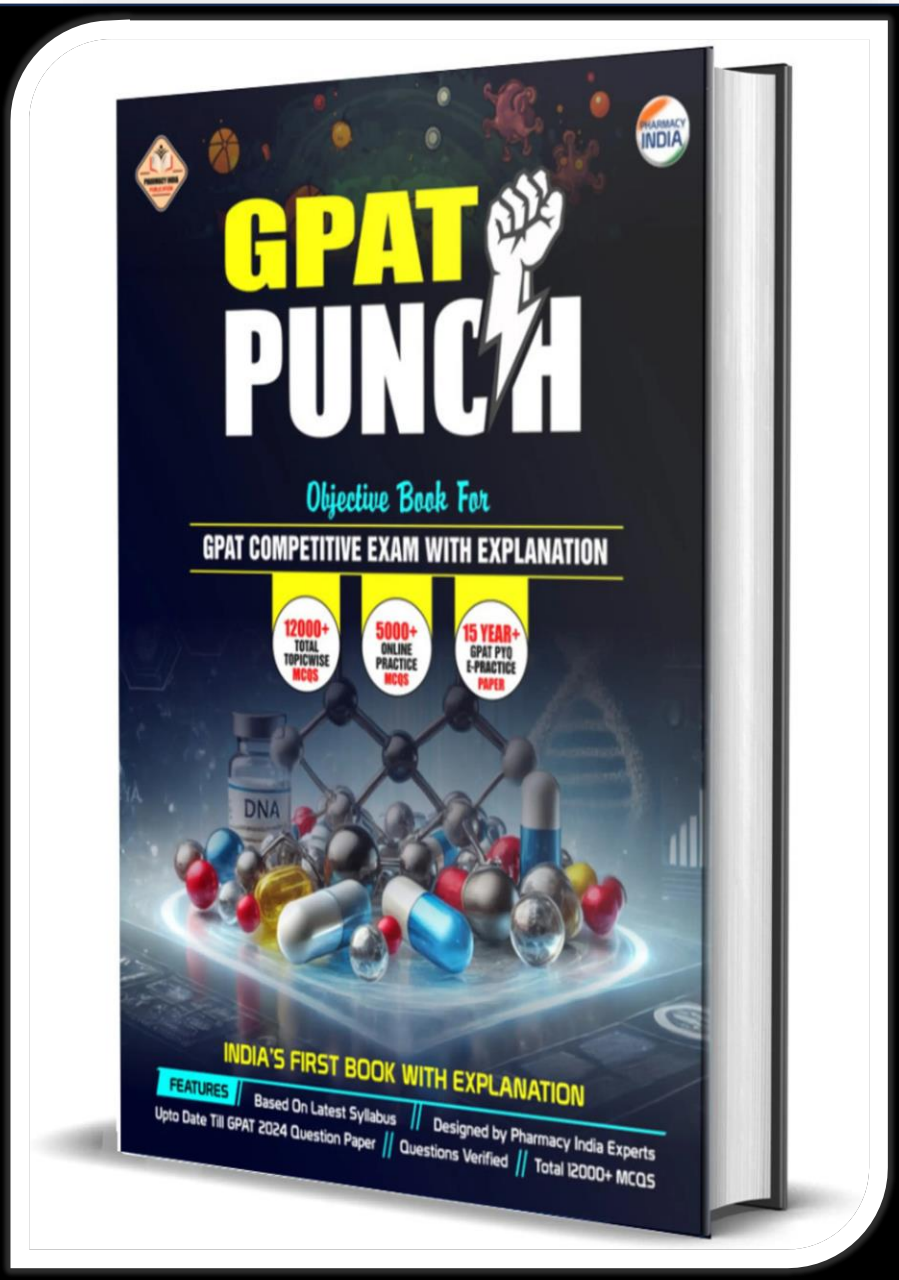

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