GPAT

2027-28

PHARMACEUTICS

CLASS- 1

PREFORMULATION

UPDATED QUESTIONS TILL GPAT 2026

GPAT

VIDEO LECTURE + PDF

STEP 1 – DOWNLOAD PHARMACY INDIA MOBILE APP FROM PLAY STORE

STEP 2 – VISIT STORE OPTION – SEARCH GPAT MANIA – ACCESS PDF + VIDEO

DAILY UPDATES

जुड़िए PHARMACY INDIA

के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

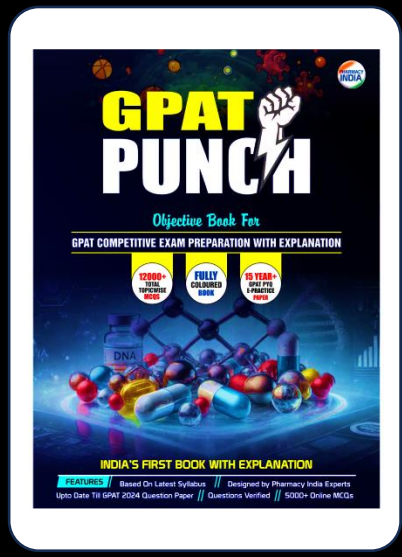
1. During preformulation, a drug shows 6% moisture uptake at 75% RH but 0.5% uptake at 40% RH. Which packaging is most suitable for long-term stability? [GPAT – 2026]

(a) HDPE bottle with silica gel

(b) PVC blister

(c) Alu – Alu blister

(d) Amber glass bottle without dessiccant



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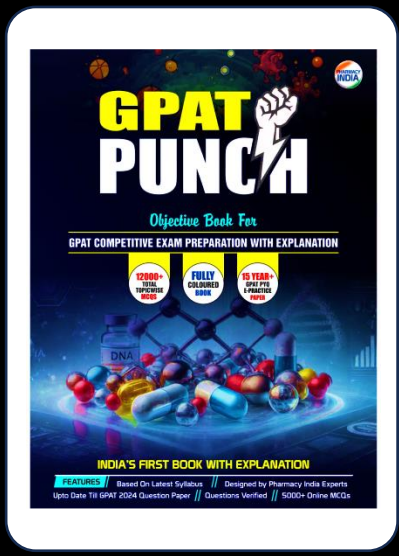


Moisture Uptake Data

- **6%** uptake at **75% RH** → High sensitivity at high humidity
- **0.5%** uptake at **40% RH** → Low sensitivity at low humidity

Drug is hygroscopic – needs maximum protection from moisture ingress.

PACKAGING OPTIONS ANALYSIS

	HDPE bottle with silica gel	Permeable to moisture over time. ✗ Not ideal
	PVC blister	High moisture vapor transmission. ✗ Not ideal
	Alu – Alu blister	Excellent barrier to moisture, light and oxygen. ✓ Most suitable
	Amber glass bottle without dessiccant	Does not protect from moisture. ✗ Not ideal

Alu – Alu blister is most suitable for long-term stability due to superior moisture barrier properties.

Key Point

For moisture sensitive drugs, choose packaging with lowest moisture permeability.

Better barrier = Better stability

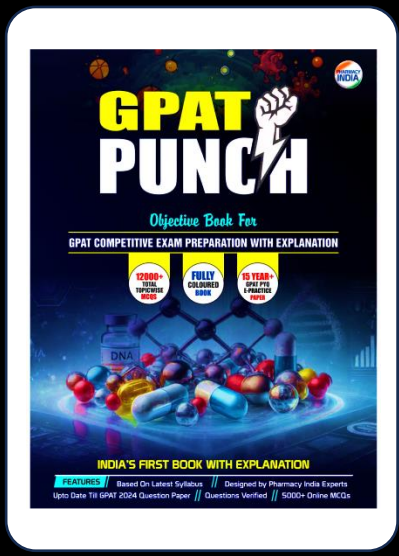
2. Which of the following molecular properties can be determined by Thermogravimetric Analysis (TGA)? [GPAT – 2023 SHIFT- I]

(a) Solubility

(b) Hygroscopicity

(c) Colour stability

(d) Hydrolysis



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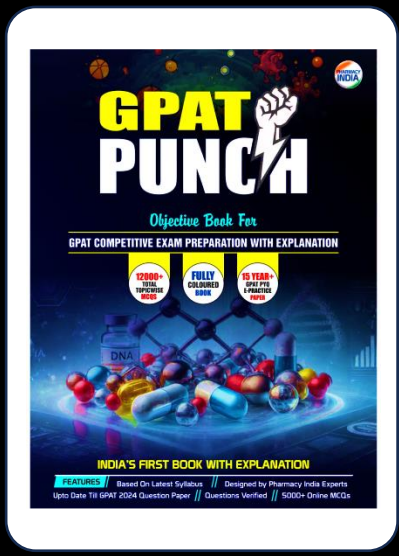


TGA → HYGROSCOPICITY

TGA measures **weight change** on heating.

Hygroscopicity = ability to **absorb moisture** from air.

MOIST SAMPLE

Adsorbed moisture

TGA HEATING

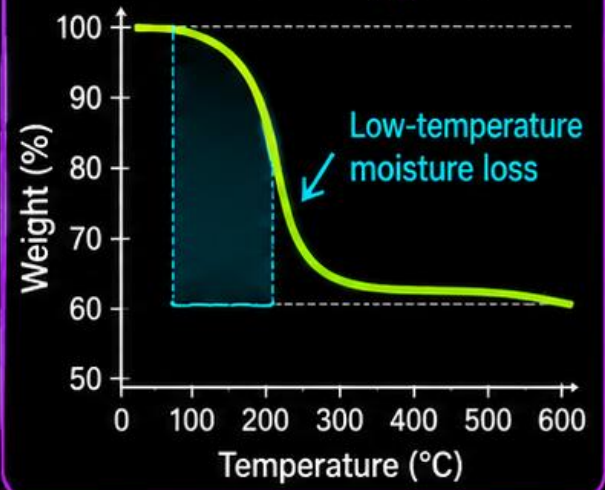
MOISTURE RELEASED

Moisture released

WEIGHT LOSS

Sample loses weight

TGA CURVE (Typical)



KEY POINT:
More absorbed moisture = **more weight loss.**

EXAM POINT:
– TGA helps detect **hygroscopic behavior.**

Not directly measured: | Solubility • Colour stability • Hydrolysis

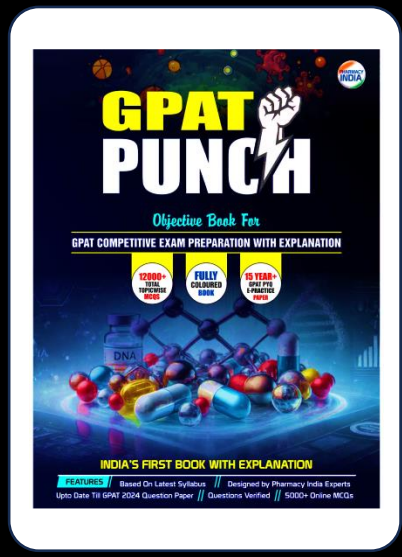
3. A crystalline powder that contains water of crystallization can liberate this water during manipulations, becoming sticky or liquefying. This is called: [GPAT – 2023 SHIFT- I]

(a) Eutectic

(b) Hygroscopic

(c) Deliquescent

(d) Efflorescent



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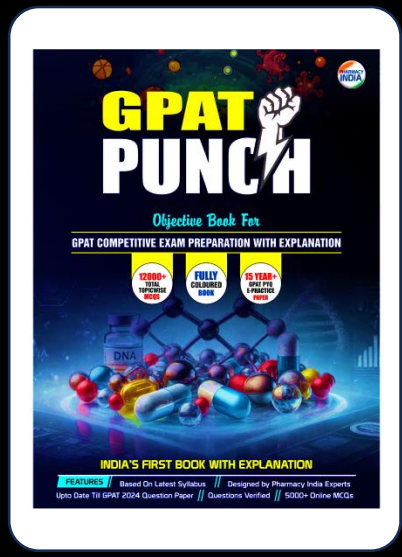


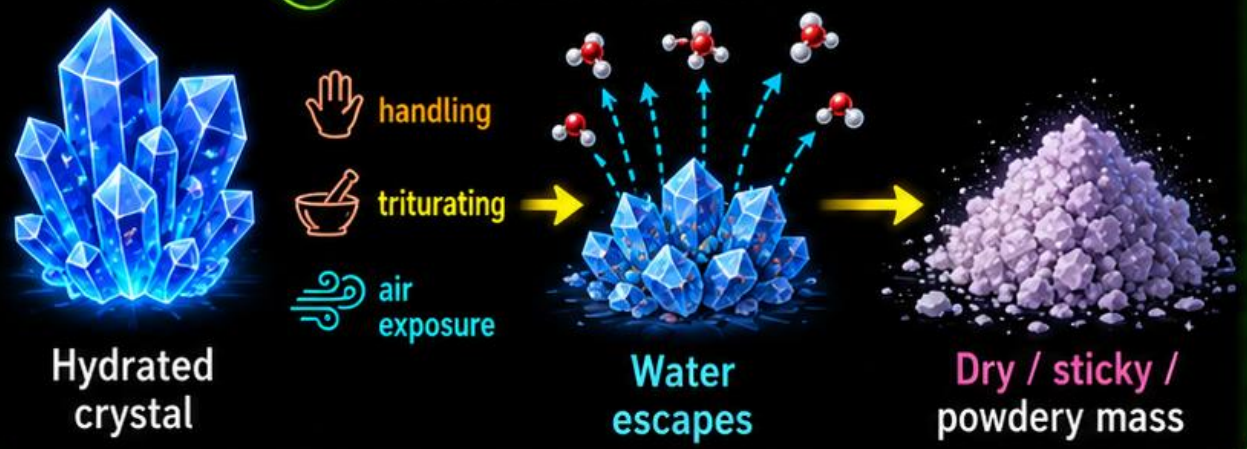
EFFLORESCENT SUBSTANCES

Loss of water of crystallization

1 MEANING

- Hydrated crystals
- Lose bound water
- On exposure or handling

2 WHAT HAPPENS



3 KEY FEATURES

- Contains water of crystallization
- Loses water on standing
- Appearance changes

4 NOT CONFUSED WITH

HYGROSCOPIC = absorbs moisture

DELIQUESCENT = absorbs + dissolves

EUTECTIC = liquefies on mixing

5 EXAMPLES

1. $Na_2CO_3 \cdot 10H_2O$
2. $Na_2SO_4 \cdot 10H_2O$
3. $CuSO_4 \cdot 5H_2O$
4. Alum $KAl(SO_4)_2 \cdot 12H_2O$

EFFLORESCENCE = LOSS OF WATER, NOT ABSORPTION

4. **Dynamic Vapour Sorption (DVS) isotherm is a plot of: [GPAT – 2021]**

(a) Crystallization Peak Energy (J/g) vs Percentage Relative Humidity

(b) Percentage Change in Mass vs Percentage Relative Humidity

(c) Crystallization Peak Energy (J/g) vs Percentage Change in Mass

(d) Crystallization Peak Energy (J/g) vs Amorphous Content

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DYNAMIC VAPOUR SORPTION (DVS) ISOTHERM

Plot of % Change in Mass vs % Relative Humidity

1. DEFINITION

DVS studies moisture interaction.

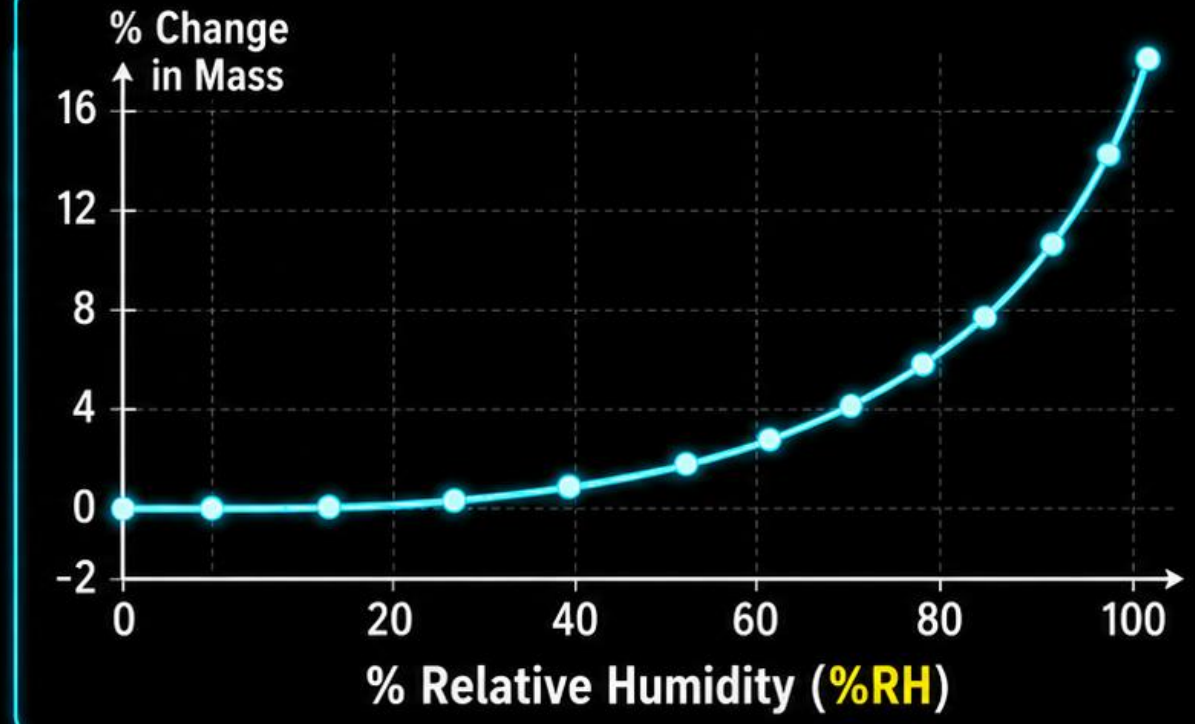
2. AXES

X: %RH

Y: % Mass Change

3. MEANING

Mass ↑ as humidity ↑



4. USE

Evaluates hygroscopicity

5. MEMORY

Humidity outside, mass inside

SAMPLE

DVS INSTRUMENT

BALANCE

ADSORPTION

DESORPTION

5. As per European Pharmacopoeia, a substance stored at 25°C for 24 hours at 80% RH is called “very hygroscopic” when the increase in weight is: [GPAT – 2020]

(a) 0.2% w/w and < 15% w/w

(b) > 0.2% w/w and < 20% w/w

(c) ≥ 15% w/w

(d) 0.2% w/w and < 2% w/w

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As per European Pharmacopoeia (Ph. Eur.)

"A substance stored at 25°C for 24 h at 80% RH is called "very hygroscopic" when the increase in weight is ≥ 15% w/w.

HYGROSCOPICITY

Ability of a substance to absorb moisture from the atmosphere.

Ph. Eur. Test Conditions

- Temperature : 25°C
- Time : 24 hours
- Relative Humidity (RH) : 80%

$$\% \text{ increase in weight (w/w)} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Ph. Eur. Classification (based on % increase in weight)

Non hygroscopic	< 0.2% w/w
Slightly hygroscopic	≥ 0.2% and < 2% w/w
Hygroscopic	≥ 2% and < 15% w/w
★ Very hygroscopic	≥ 15% w/w
Deliquescent	≥ 20% w/w

CONCLUSION

A substance is called "very hygroscopic" when the increase in weight is ≥ 15% w/w under 25°C, 24 h, 80% RH.

★ Mnemonic ★

"15 or more, Very for sure!"

Key Takeaway : ≥ 15% w/w increase in weight at 25°C/24 h/80% RH = Very hygroscopic

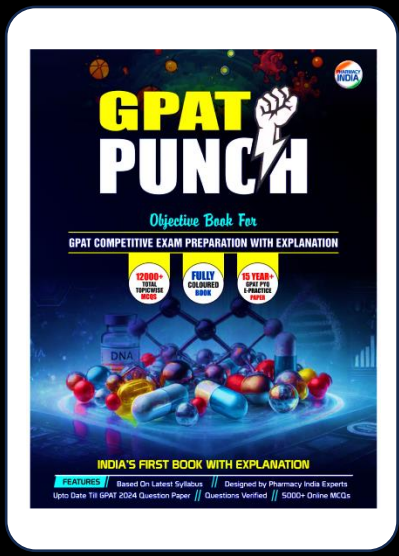
6. **Polymorphs exhibit different physical properties EXCEPT: [GPAT – 2020]**

(a) X-ray crystal and diffraction patterns

(b) Melting points

(c) Solubilities

(d) Chemical structures



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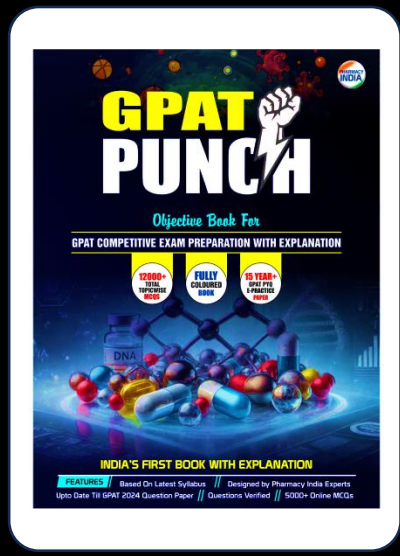
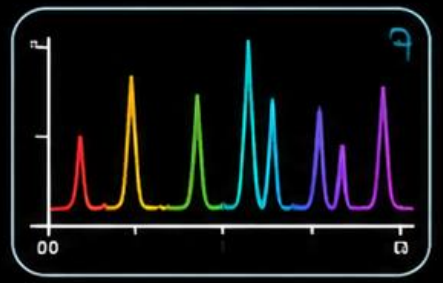


POLYMORPHS – DIFFERENT PHYSICAL PROPERTIES EXCEPT

Polymorphs = Same chemical compound, different crystal arrangement

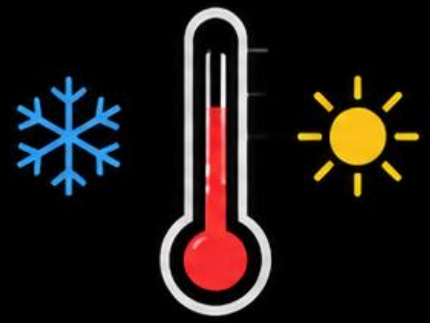
PHYSICAL PROPERTIES THAT VARY

X-ray crystal & diffraction patterns



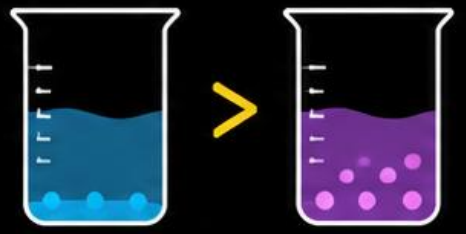
Different crystal packing gives different patterns

Melting points



Different stability → different melting points

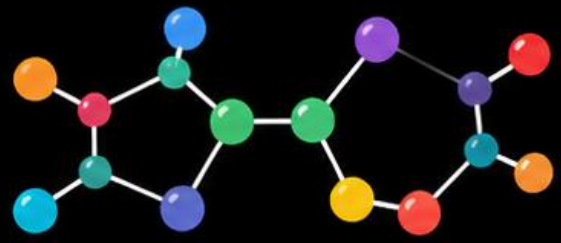
Solubilities



Different packing → different solubility

EXCEPT

Chemical structures



Chemical structure remains the same

Polymorphs: Different XRD patterns | Different Melting points | Different Solubilities | Same Chemical structure

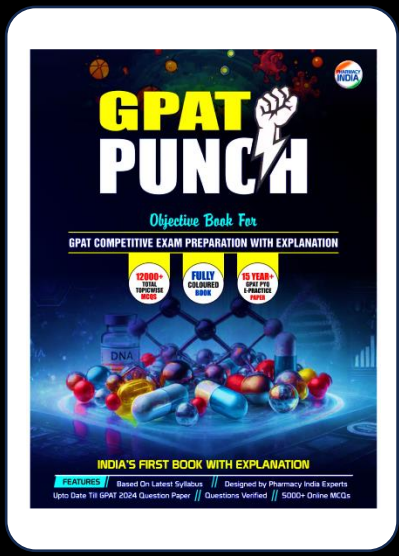
7. While studying solid-state physicochemical properties, the "packing property" of a drug includes: [GPAT – 2020]

(a) Heat capacity

(b) Solubility

(c) Refractive index

(d) Entropy



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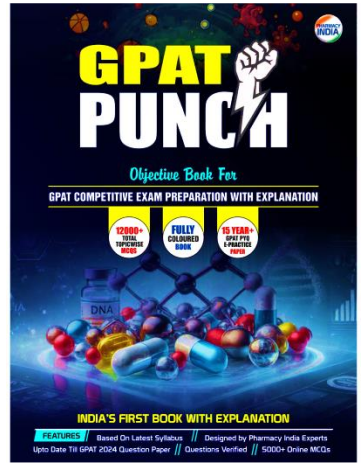
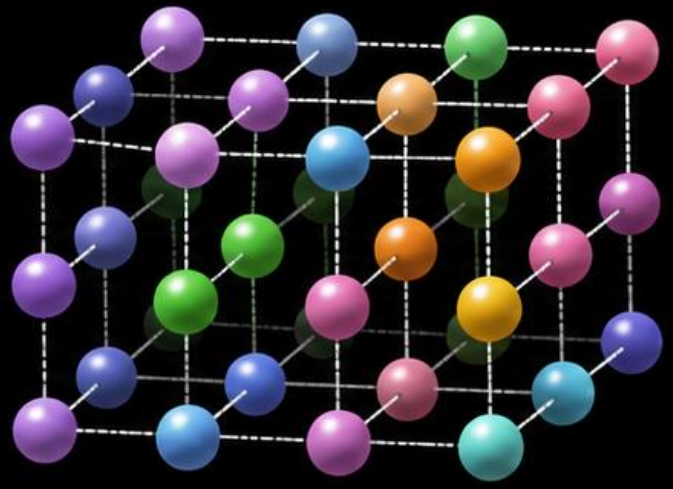
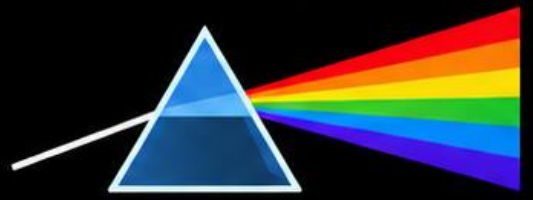


Packing Property in Solid-State

Packing property refers to how molecules are arranged in a crystal lattice.





Refractive index depends on how tightly molecules are packed in the solid state.

Correct Answer

Refractive index is a key **packing property**.

Key Takeaway: **Packing property** of a drug → **Refractive index**

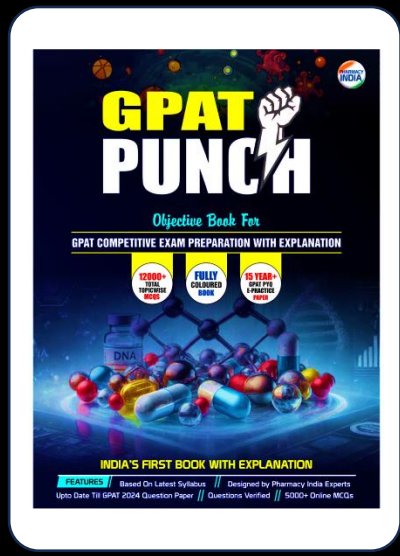
8. **Which polymorphic form of a drug candidate has the highest melting point? [GPAT – 2019]**

(a) Unstable

(b) Metastable

(c) Hydrates

(d) Stable



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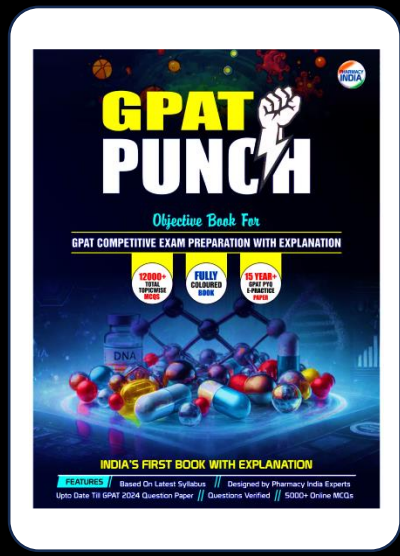
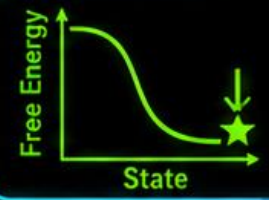


Stable Polymorph = Highest Melting Point



Stable form has **lowest** free energy.

1. More ordered
2. Tighter packing
3. Stronger lattice
4. More heat needed

→ **Highest melting point**

STABLE	METASTABLE	UNSTABLE
Most ordered	Less ordered	Least ordered
Highest MP	Intermediate MP	Lowest MP

★ EXAM PEARL

Stable polymorph usually **melts** at the **highest** temperature.

⚠ NOTE

Chemical **structure** same, crystal **arrangement** different.

Lower free energy → better packing → stronger lattice → more heat → higher melting point

9. **In preformulation studies, polymorphs can be detected by:**

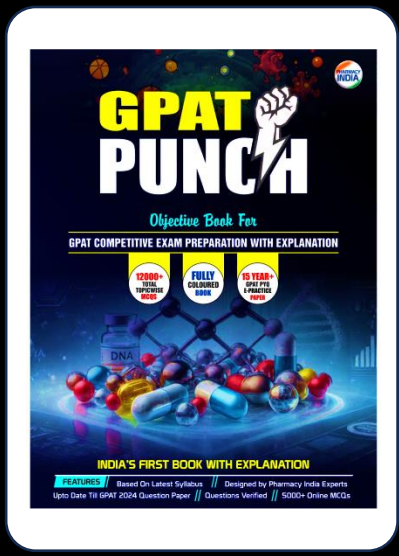
[GPAT – 2019]

(a) Counter current chromatography

(b) Refractometry

(c) High performance liquid chromatography

(d) Differential scanning calorimetry (DSC)



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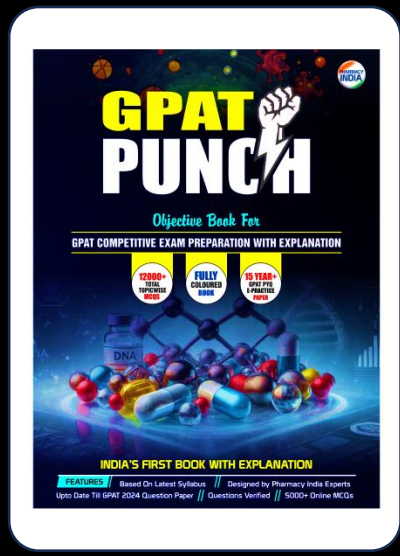


Polymorphs in Preformulation Studies

Polymorphs = Same chemical entity, different crystal lattice → **different properties**

WHY DETECT POLYMORPHS?

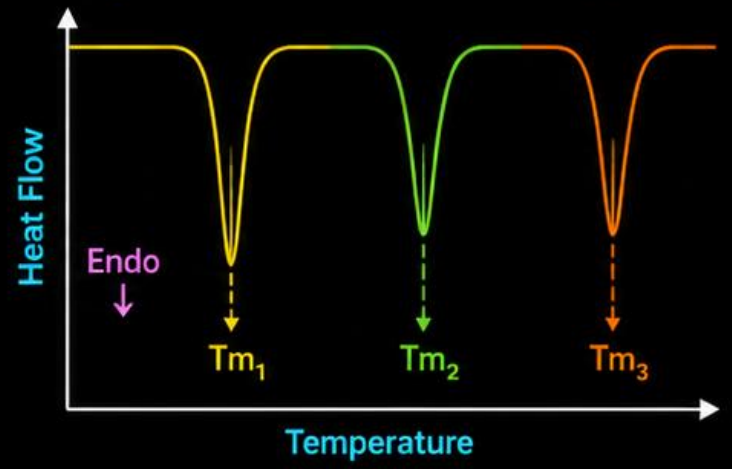
Affects solubility, stability, bioavailability & manufacturability

DSC PRINCIPLE

Measures heat flow associated with thermal transitions. Different polymorphs show different melting points and enthalpy.

DETECTION BY DSC

Each polymorph gives a unique melting endotherm (Tm) and enthalpy (ΔH).



★ Unique Tm and ΔH = Fingerprint for each polymorph

OTHER METHODS & LIMITATIONS

Counter Current Chromatography	Separation technique, not specific for polymorphs ✗
Refractometry	Measures refractive index; cannot distinguish polymorphs ✗
High Performance Liquid Chromatography	Analyzes purity/ impurities; not for solid-state polymorphs ✗
Differential Scanning Calorimetry (DSC)	Detects different melting behavior → best method for polymorph detection ✓

KEY TAKEAWAY: Different polymorphs → Different thermal behavior → DSC gives unique thermal fingerprint → Hence, DSC is the method of choice

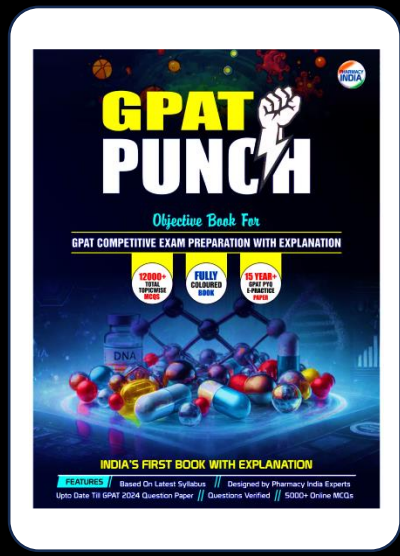
10. **Phase solubility analysis curve is NOT a good tool for: [GPAT – 2019]**

(a) Complex formation

(b) Bioavailability determination

(c) Polymorph detection

(d) Impurity detection



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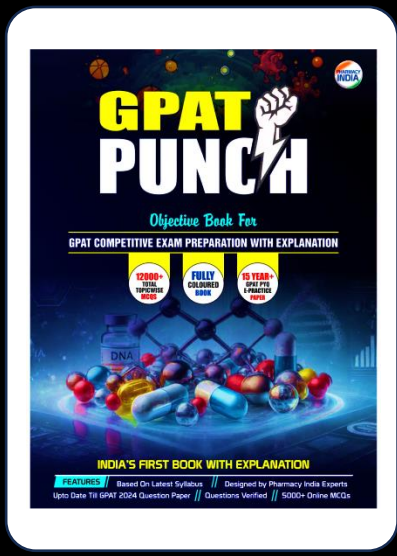


PHASE SOLUBILITY CURVE

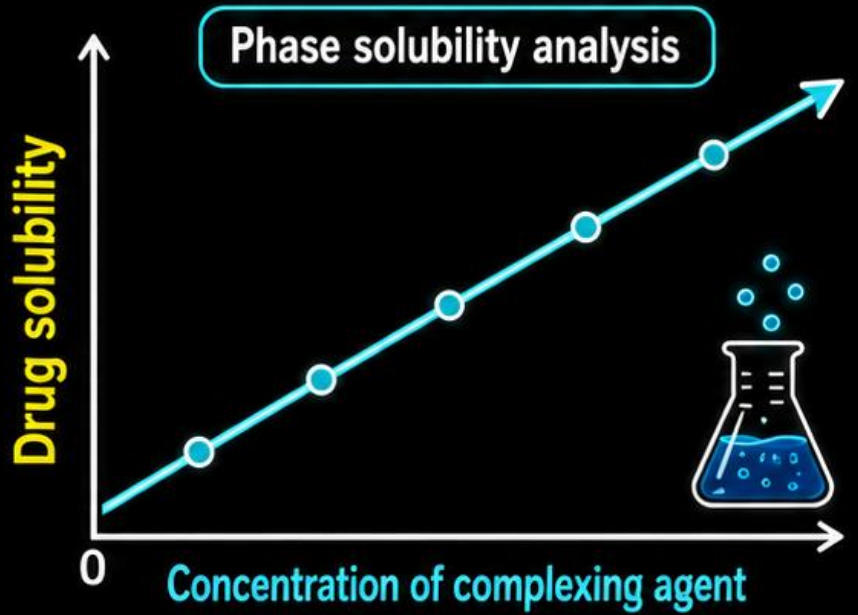
Not for Bioavailability Determination

1 WHAT IT STUDIES

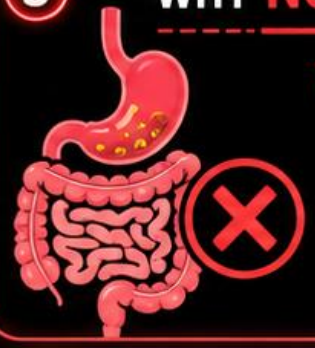
- Shows change in **drug solubility** with **complexing agent**.

2 USEFUL FOR

- **Complex** formation, **stability** constant, solubility **behavior**.



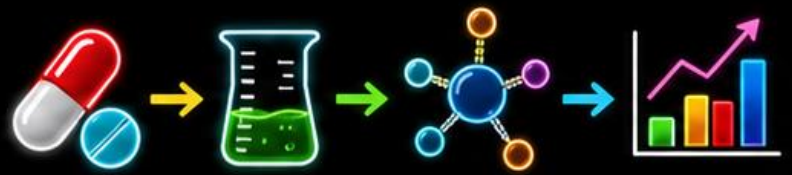
3 WHY NOT BIOAVAILABILITY?



- **Bioavailability** depends on **absorption**, **permeability**, **metabolism** and *in-vivo* factors.

4 KEY POINT

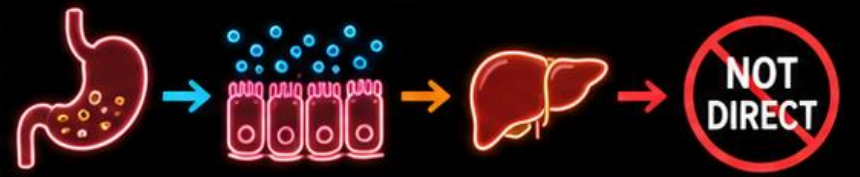
- Phase solubility is an ***in-vitro*** **solubility tool**, not a direct *in-vivo* **bioavailability test.**



REMEMBER:

SOLUBILITY ≠ BIOAVAILABILITY

Good for preformulation, ***not*** for direct **BA** determination.



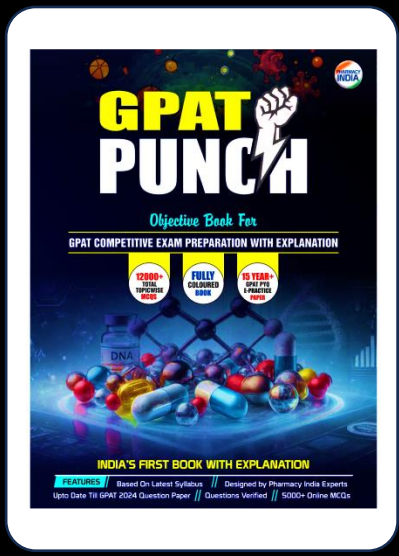
11. **Which of the following techniques is NOT useful to detect polymorphs? [GPAT – 2017]**

(a) DSC

(b) HPLC

(c) PXRD

(d) Melting point determination



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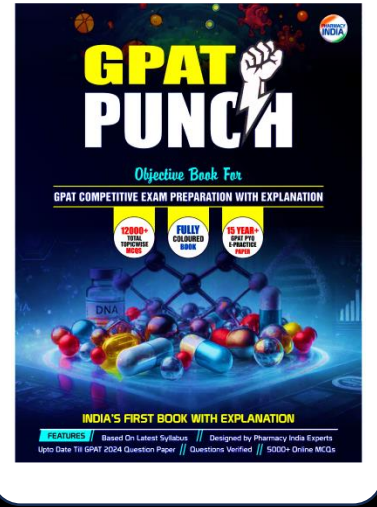
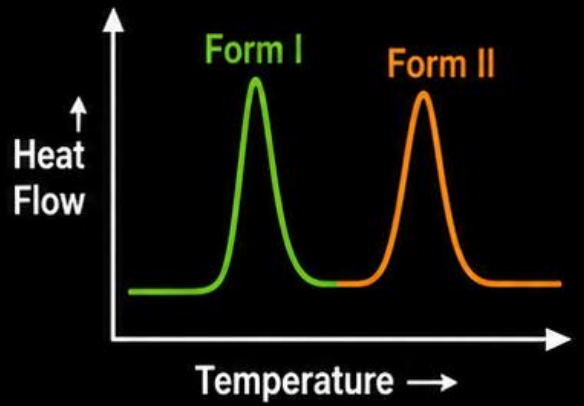


Why HPLC is NOT useful to detect polymorphs

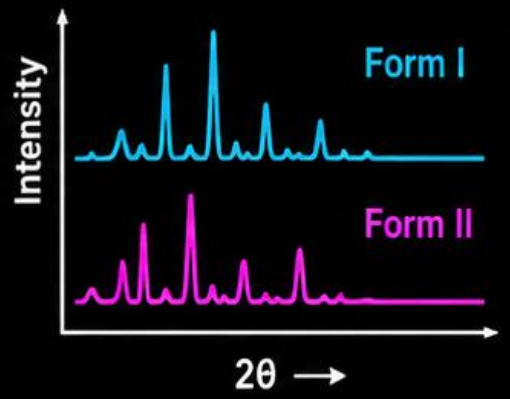
DSC



Different melting behavior

Useful

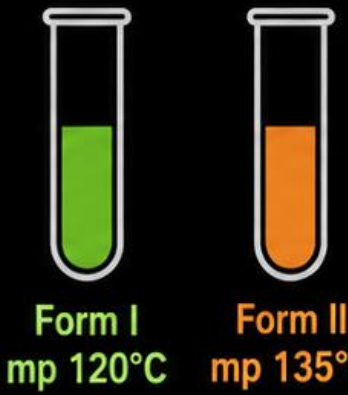
PXRD



Different diffraction pattern

Useful

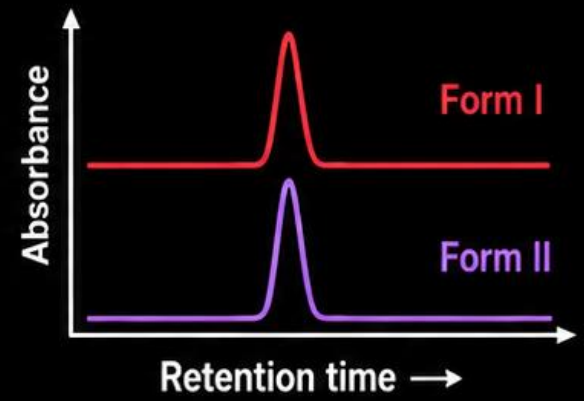
Melting Point



Different melting point

Useful

HPLC



Same retention time (No difference)

NOT Useful

HPLC separates based on **chemical properties**, polymorphs have **same chemical identity**.

HPLC cannot distinguish polymorphs.

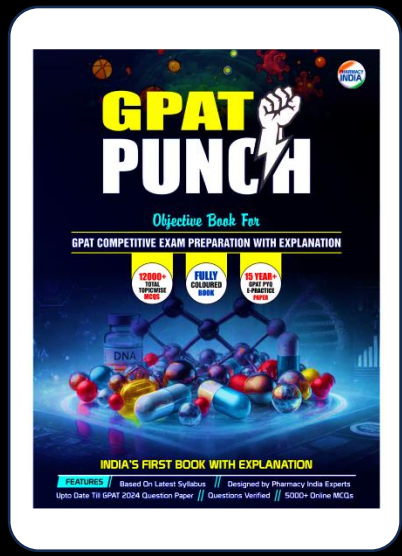
12. **Hot stage microscopy is an important tool in preformulation studies for the study of: [GPAT – 2013, 2017]**

(a) Pseudopolymorphism

(b) Particle size measurement

(c) Microbial contamination

(d) Compaction behavior



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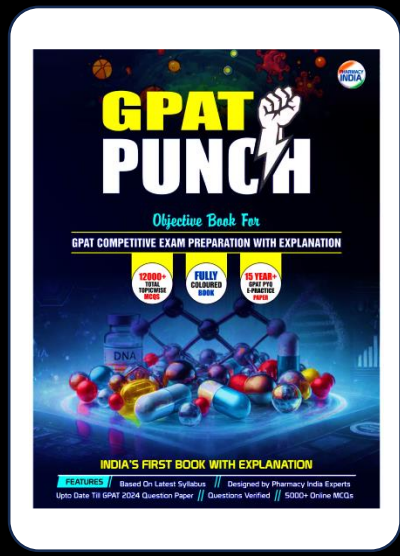


HOT STAGE MICROSCOPY → PSEUDOPOLYMORPHISM

PHARMACY INDIA

Important preformulation tool

Hot stage microscopy = microscope + **heating stage** used to observe changes during heating.

Pseudopolymorphism = crystal forms **containing solvent** or **water**, such as **hydrates / solvates**.

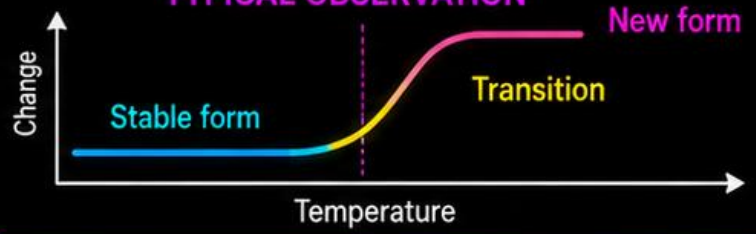
1. CRYSTAL ON HEATED STAGE

2. HEAT APPLIED

3. SOLVENT / WATER LEAVES CRYSTAL

4. CRYSTAL FORM CHANGES

TYPICAL OBSERVATION



EXAM POINT:

Best for studying **hydrate / solvate** behavior

WHY CORRECT?

- Tracks crystal **changes** on heating
- Detects **hydrate / solvate** loss
- Shows **phase transition** visually
- Useful for **pseudopolymorphic** forms

NOT FOR: Particle size | Microbial contamination | Compaction behavior

13. **The solvates can exist in different crystalline forms called:**

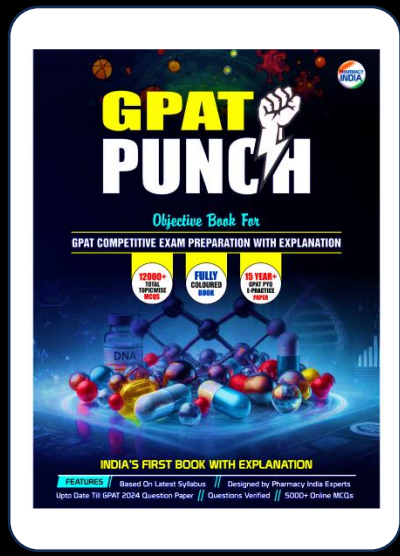
[GPAT – 2015]

(a) Enantiotropic

(b) Monotropic

(c) Pseudopolymorphs

(d) Amorphous



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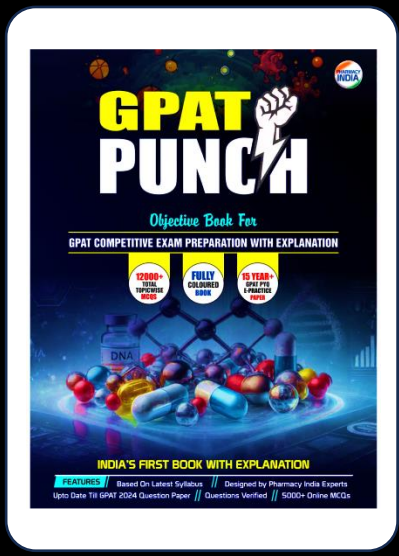


PSEUDOPOLYMORPHS

Different crystalline forms of solvates

1. MEANING

Solvates = crystals containing solvent molecules

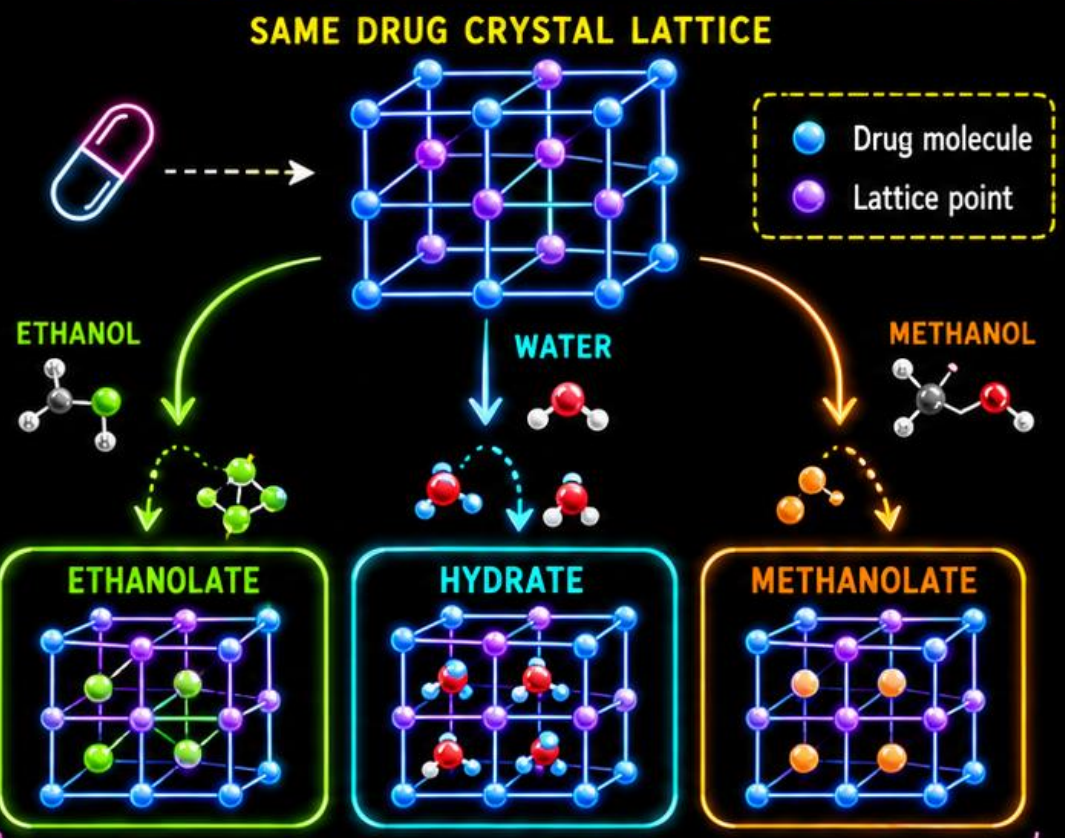
When water is present → **hydrate**

2. KEY CONCEPT

Same drug + different included solvent

→ different **crystal forms**

These forms are called **pseudopolymorphs**



4. WHY NOT OTHERS?

Enantiotropic / Monotropic = relation between polymorphs

Amorphous = no crystal lattice

SOLVATES IN DIFFERENT CRYSTALLINE FORMS = PSEUDOPOLYMORPHS

14. Which of the following is a thermodynamic property of a drug?

(a) Refractive index

(b) Density

(c) Solubility

(d) Molar volume

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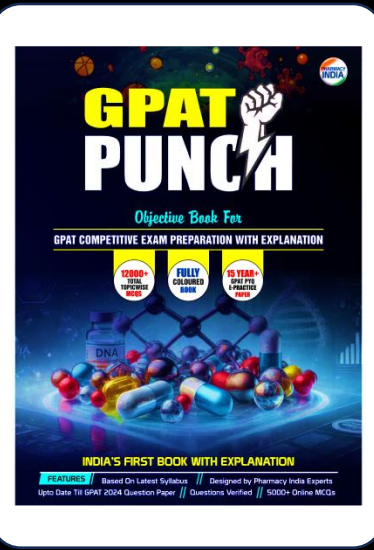


Why SOLUBILITY is a Thermodynamic Property?

Thermodynamic properties depend on the **energy** and **equilibrium** of the system and change with **temperature**, **pressure** or **composition**.

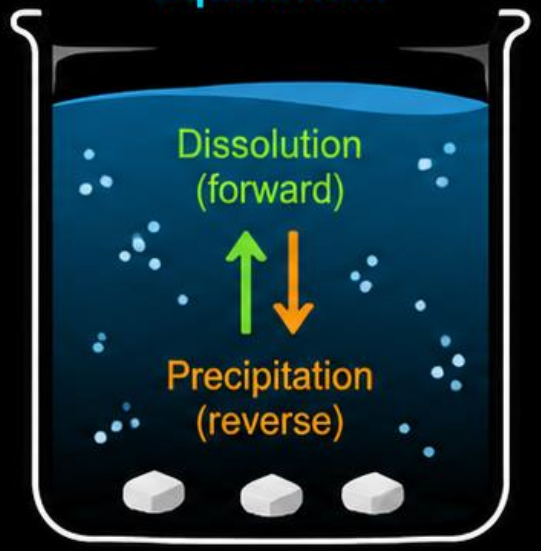
✗ **Refractive index**
Optical property.
Does not depend on thermodynamic equilibrium.

✗ **Density**
Physical property.
Not governed by energy or equilibrium.

✓ **Solubility**
Depends on Gibbs free energy ($\Delta G = \Delta H - T\Delta S$) and is at equilibrium.

✗ **Molar volume**
Derived physical property.
Not an equilibrium property.

Equilibrium



At equilibrium,
$\Delta G = 0$ → Solubility is thermodynamic in nature.

Why Solubility is Thermodynamic?

- Changes with **temperature** (endothermic/exothermic dissolution)
- Changes with **pressure** (especially for gases)
- Represents an **equilibrium** between solid and dissolved state

Takeaway: Solubility reflects the **energy** and **equilibrium** of a system → a true **thermodynamic property**.

Correct Answer: (c) Solubility

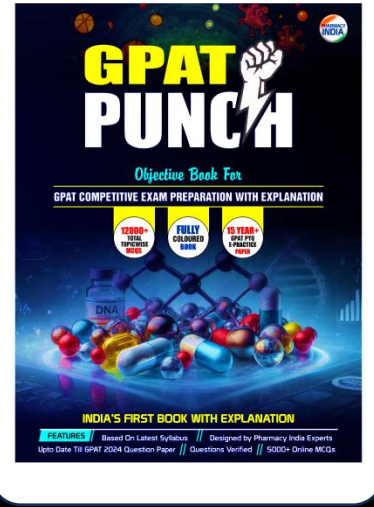
15. **Preformulation studies ensure which of the following?**

(a) Efficacy

(b) Stability

(c) Safety

(d) All of the above



15. **Preformulation studies ensure which of the following?**

(a) Efficacy

(b) Stability

(c) Safety

(d) All of the above

Preformulation Studies

Ensure...

Drug Substance

Preformulation Studies

Safe, Effective & Stable Product

Efficacy

Ensures the drug produces the desired therapeutic effect.

Stability

Ensures the drug remains stable throughout its shelf life.

Safety

Ensures the drug is non-toxic and safe for use.

Conclusion:

Preformulation studies ensure Efficacy, Stability, Safety, and All of the above.

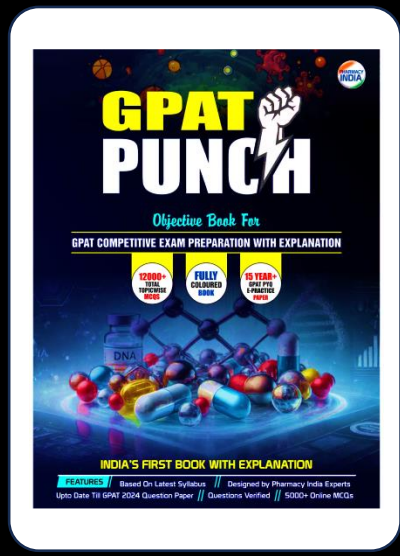
16. **SEM (Scanning Electron Microscopy) is used in preformulation to analyze:**

(a) Crystallinity and solubility

(b) Flow property

(c) Shape and size

(d) Complexity



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SEM IN PREFORMULATION

ANALYZES SHAPE & SIZE

SEM = Scanning Electron Microscopy

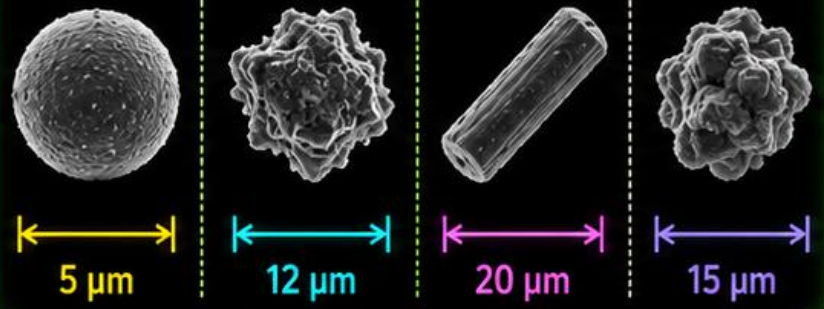
Gives detailed surface images.

Used to study particle **SHAPE** and **SIZE**

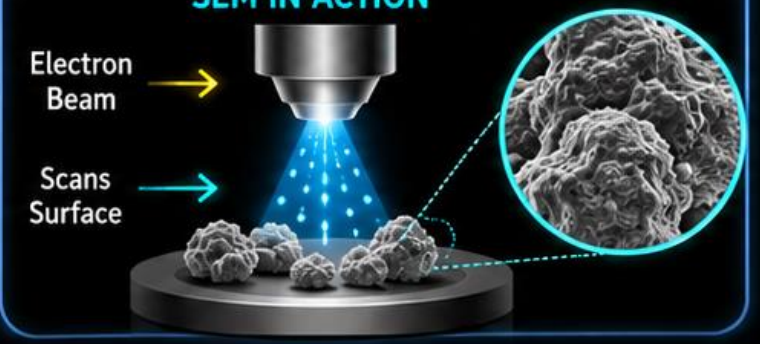
WHY IMPORTANT

☑ **Shape** and **size** affect **flow**, **packing**, and **formulation** behavior.

DIFFERENT PARTICLE SHAPES (with size)



SEM IN ACTION



QUICK NOTE

SEM shows **morphology**, not **solubility** or **complexity**.

Remember: SEM → morphology = shape + size

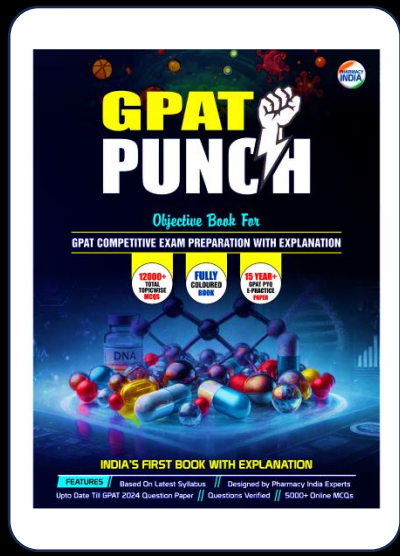
17. **Bragg's law is used to define:**

(a) Solubility

(b) Shape

(c) X-ray Diffraction

(d) Particle size



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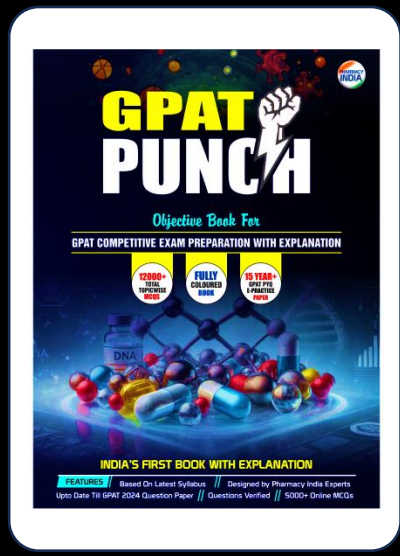
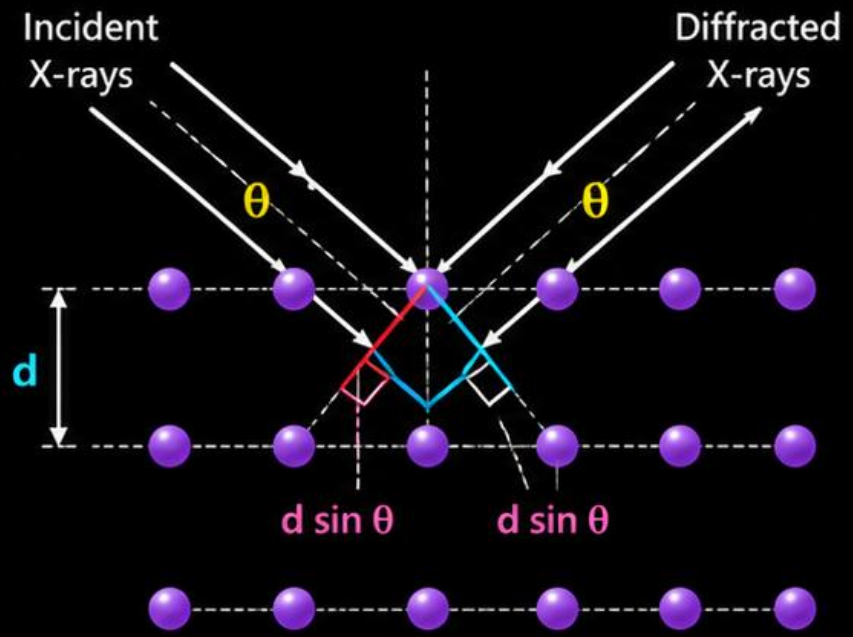


Bragg's Law Defines X-ray Diffraction

Bragg's law relates the angle of incidence of X-rays to the spacing between crystal planes.

X-rays incident on crystal planes



Bragg's Law

$$n\lambda = 2d \sin\theta$$

- n = Order of diffraction (1, 2, 3 ...)
- λ = Wavelength of X-ray
- d = Distance between planes
- θ = Angle of incidence

Used to Define:

X-ray Diffraction

Analyzes crystal structures by diffraction pattern.

Key Takeaway: Bragg's law is used to define **X-ray Diffraction**.

18. According to USP, “sparingly soluble” means parts of solvent required for one part of solute is:

(a) 1–10

(b) 10–30

(c) 30–100

(d) 100–1000

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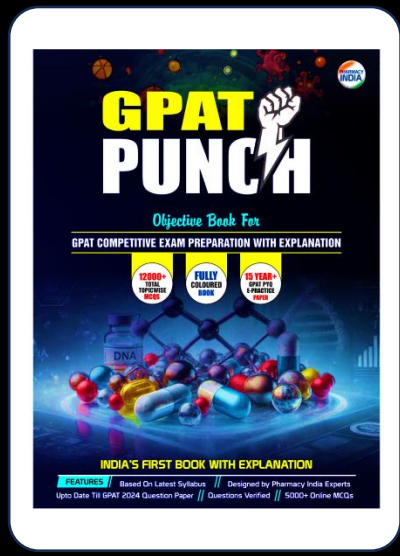


USP Solubility Classification

🎯 Definition (USP)

"Sparingly soluble" means 30–100 parts of solvent are required for one part of solute.

More solvent, less soluble

Solubility Term (USP)	Parts of Solvent Required for 1 Part of Solute
Very soluble	< 1
Freely soluble	1 – 10
Soluble	10 – 30
Sparingly soluble	30 – 100
Slightly soluble	100 – 1000
Very slightly soluble	1000 – 10,000
Practically insoluble	> 10,000

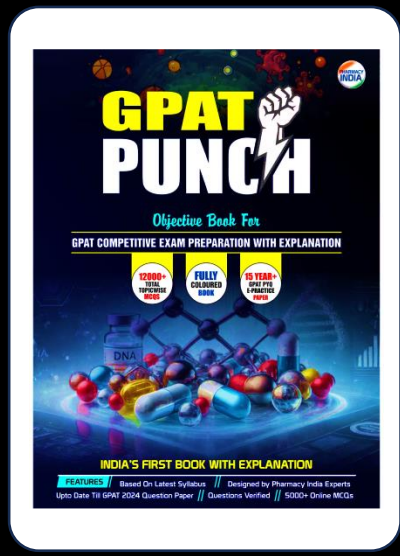
19. **The ratio of void volume to bulk volume is known as:**

(a) Bulk density

(b) Tapped density

(c) Porosity

(d) Granule volume



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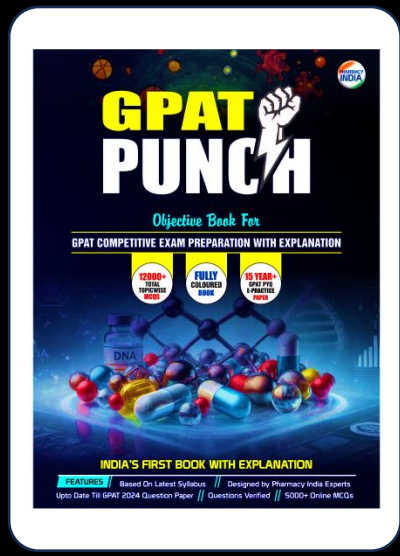


POROSITY

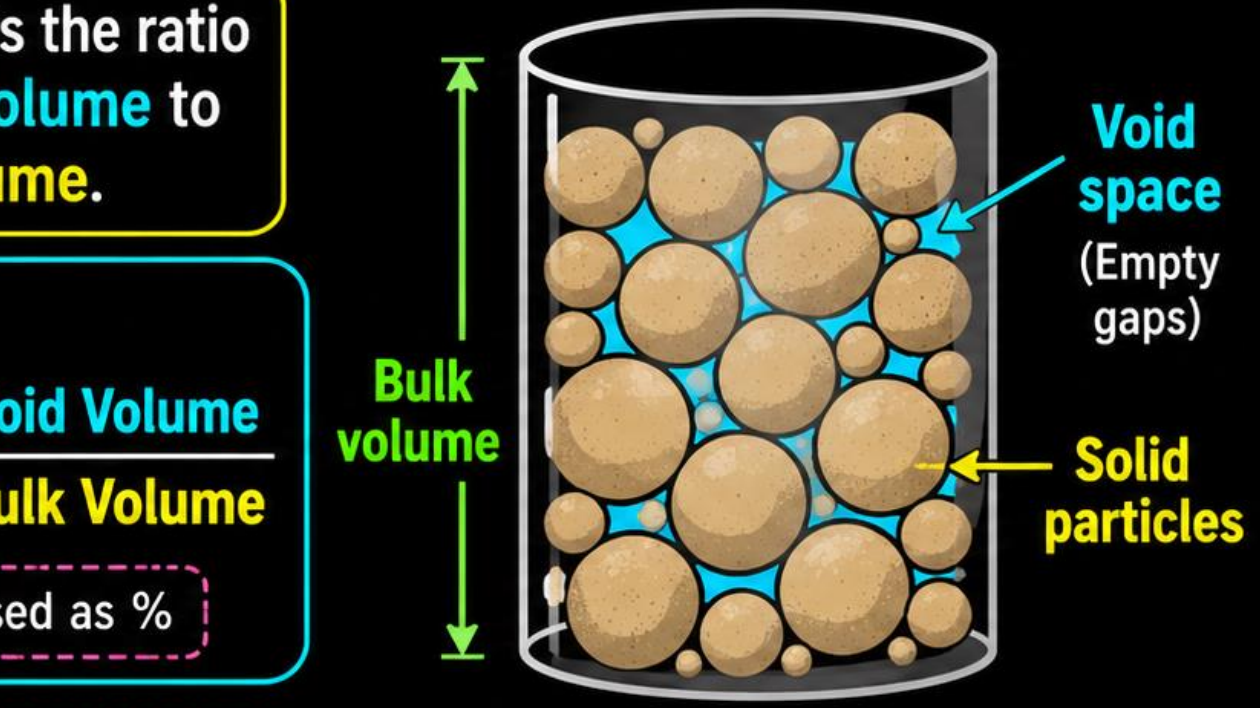
DEFINITION

Porosity is the ratio of **void volume** to **bulk volume.**

FORMULA

$$\text{Porosity } (\varepsilon) = \frac{\text{Void Volume}}{\text{Bulk Volume}}$$

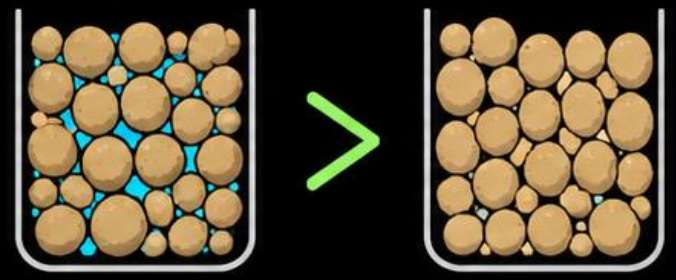
×100 if expressed as %



EXPLANATION

Shows how much empty space is present inside a powder bed or granules.

COMPARISON CUE



RELATED TO

KEY TAKEAWAY

Higher void space = Higher porosity

CORRECT ANSWER CONCEPT: POROSITY

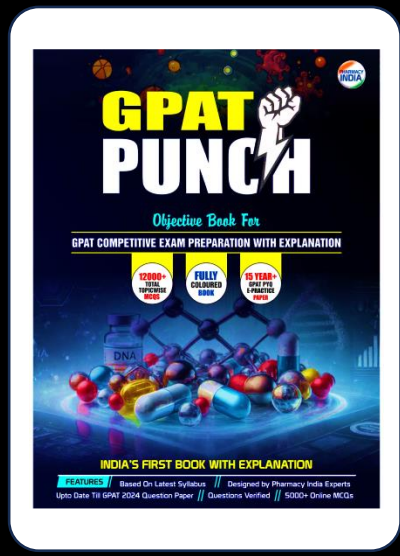
20. **Hausner Ratio is defined as:**

(a) Tapped density / Bulk density

(b) Bulk density / Tapped density

(c) Bulk volume / Void volume

(d) Void volume / Bulk volume



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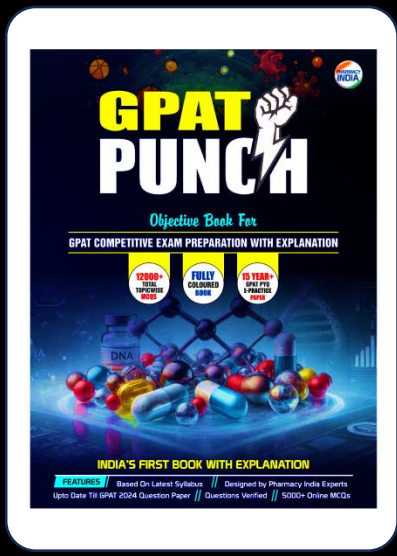
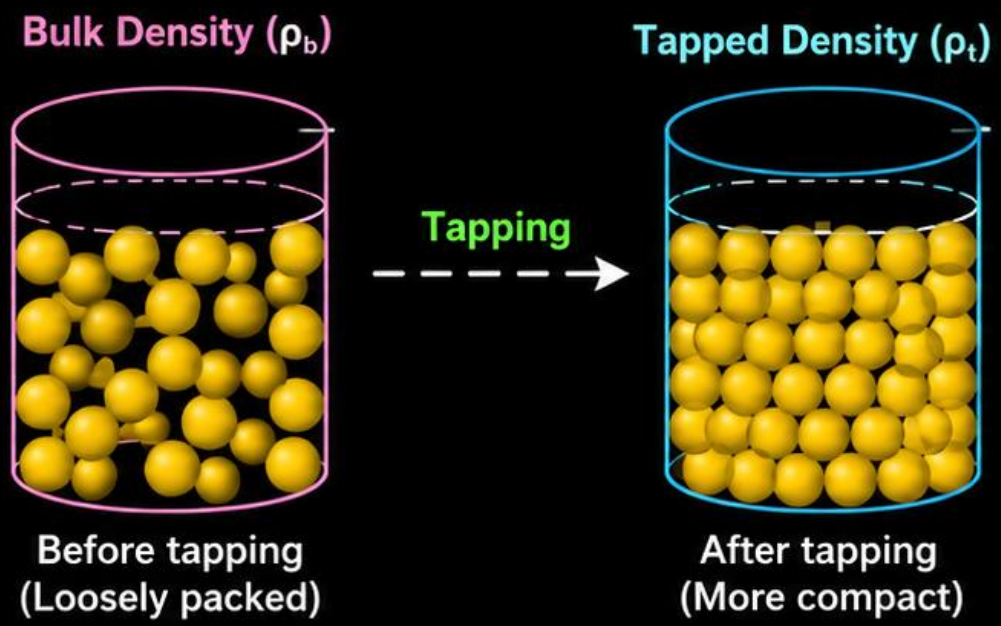


HAUSNER RATIO

Definition

$$\text{Hausner Ratio (HR)} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$



Importance

Indicates **flowability** of powder

Interpretation (HR)

- ≤ 1.25 : Excellent flow
- 1.25 – 1.50 : Good flow
- 1.50 – 1.75 : Fair flow
- > 1.75 : Poor flow

Key Point

Higher HR ↓ Poorer flowability

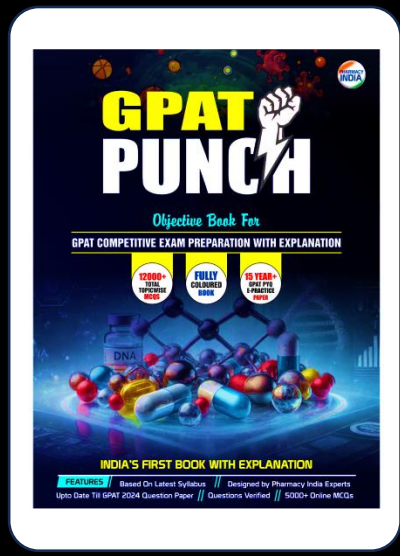
21. **Intrinsic dissolution rate is mainly expressed as:**

(a) mg/mL

(b) mg/cm²/min

(c) mg/kg

(d) mEq/L



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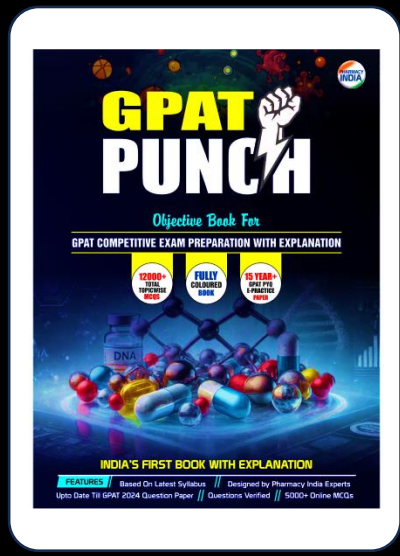


Intrinsic Dissolution Rate (IDR)

Intrinsic Dissolution Rate (IDR): The rate at which a drug dissolves from a unit surface area of solid in a given time, under sink conditions.

Concept

Expression

$$IDR = \frac{\text{Amount of drug dissolved (mg)}}{\text{Surface area (cm}^2\text{)} \times \text{Time (min)}}$$

Unit: $mg/cm^2/min$

Therefore, **Intrinsic Dissolution Rate** is mainly expressed as $mg/cm^2/min$

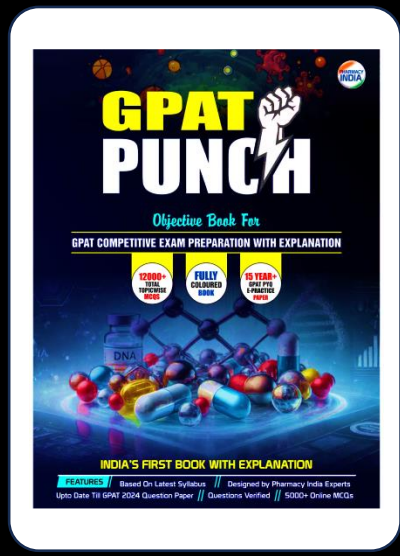
22. **The main purpose of pH–solubility profile in preformulation is to study:**

(a) Drug colour

(b) Solubility behavior with pH

(c) Particle shape

(d) Bulk density



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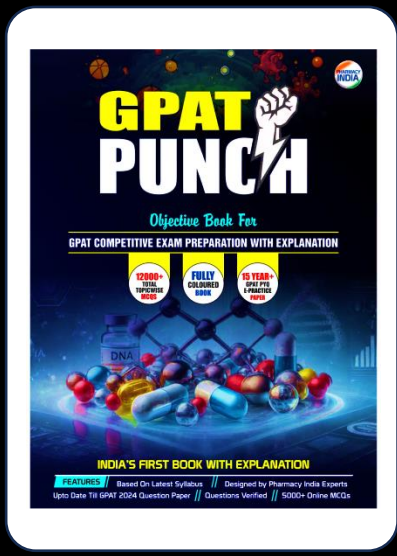
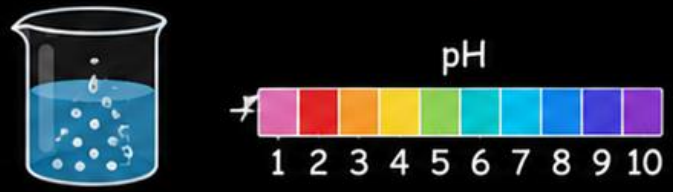


Purpose of pH–Solubility Profile in Preformulation

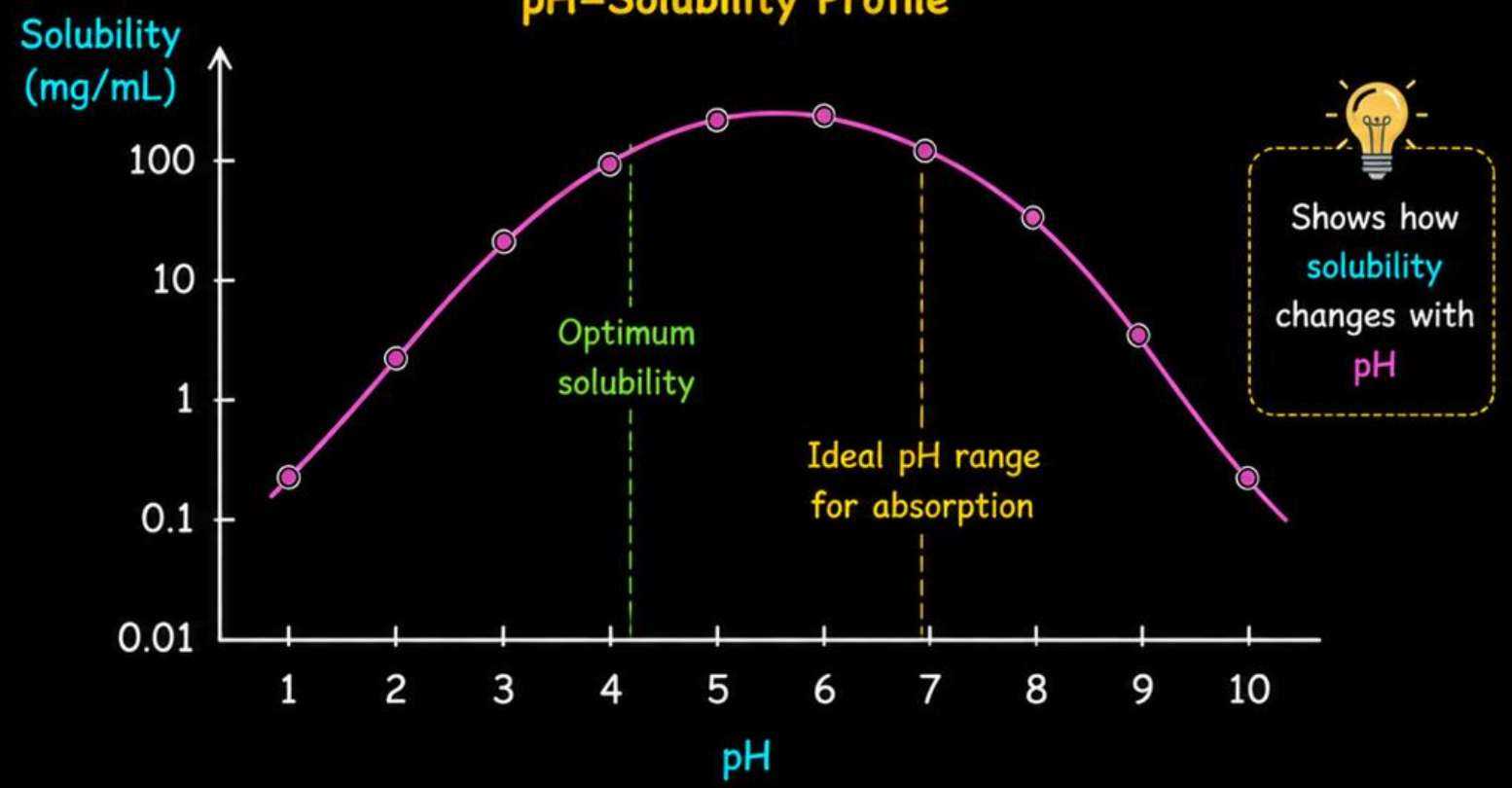
Main Purpose

To study
Solubility behavior
of drug with **pH**



- Essential for selecting optimum pH for absorption
- Helps in dose form development

pH–Solubility Profile



Shows how solubility changes with pH

Key Takeaway: pH–solubility profile helps to understand and predict how drug solubility varies with pH, guiding optimal formulation and better bioavailability.

23. **Which of the following can Coulter Counter analyze?**

(a) Size distribution

(b) Crystallinity

(c) Functional groups

(d) Flow property

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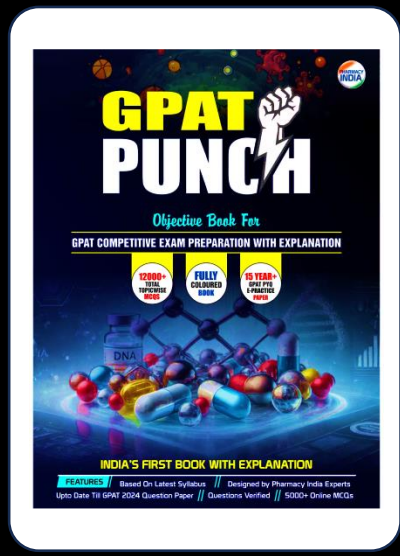


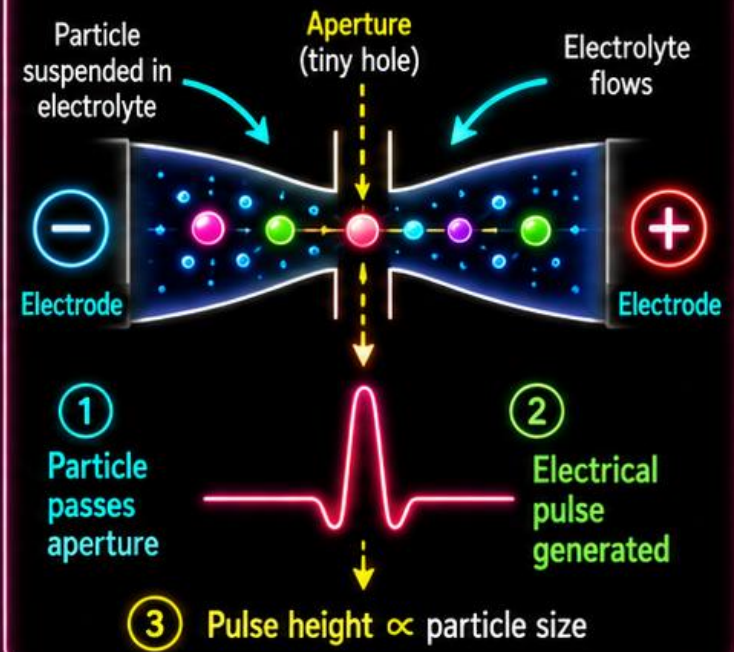
COULTER COUNTER

Analyzes particle size distribution

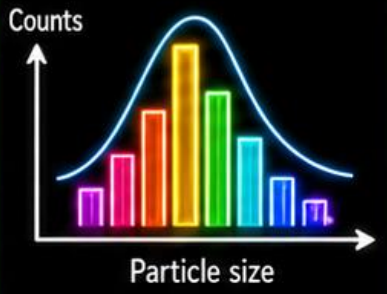
1 WHAT IT MEASURES

- Counts particles
- Measures particle volume
- Gives size distribution

2 WORKING PRINCIPLE



3 OUTPUT



- Pulse count = number of particles
- Pulse size = particle size
- Final output: size distribution curve

4 WHY CORRECT

- Best for particle sizing
- Useful in preformulation
- Rapid and quantitative

5 NOT USED FOR

- Crystallinity → XRD / DSC
- Functional groups → IR
- Flow property → angle of repose / Hausner ratio

COULTER COUNTER = SIZE DISTRIBUTION, NOT CRYSTALLINITY OR FUNCTIONAL GROUPS

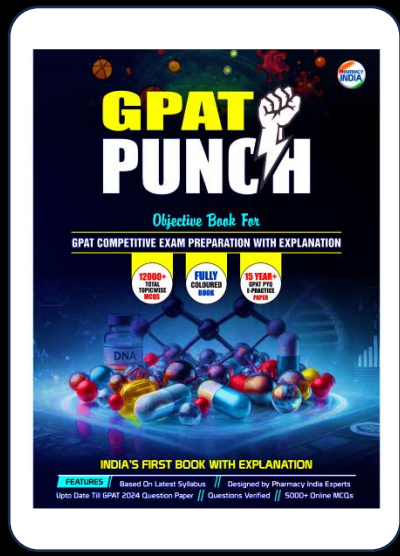
24. **Micronization of a drug substance increases its:**

(a) Particle size

(b) Surface area

(c) Bioactivity

(d) Duration of action



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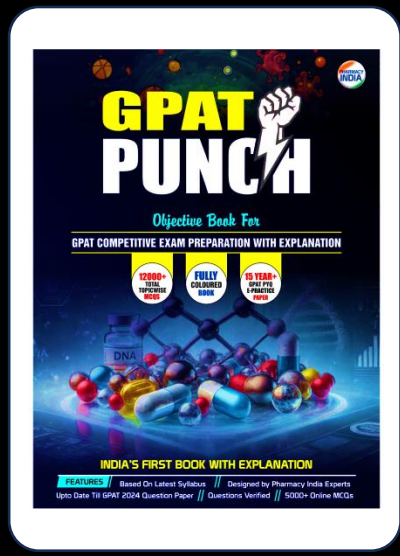
(d) Duration of action



MICRONIZATION OF DRUG SUBSTANCE

Smaller particle size → Larger surface area

DEFINITION:

Micronization reduces particle size to the **micron range (≈ 1–10 µm)**.

CONCEPT

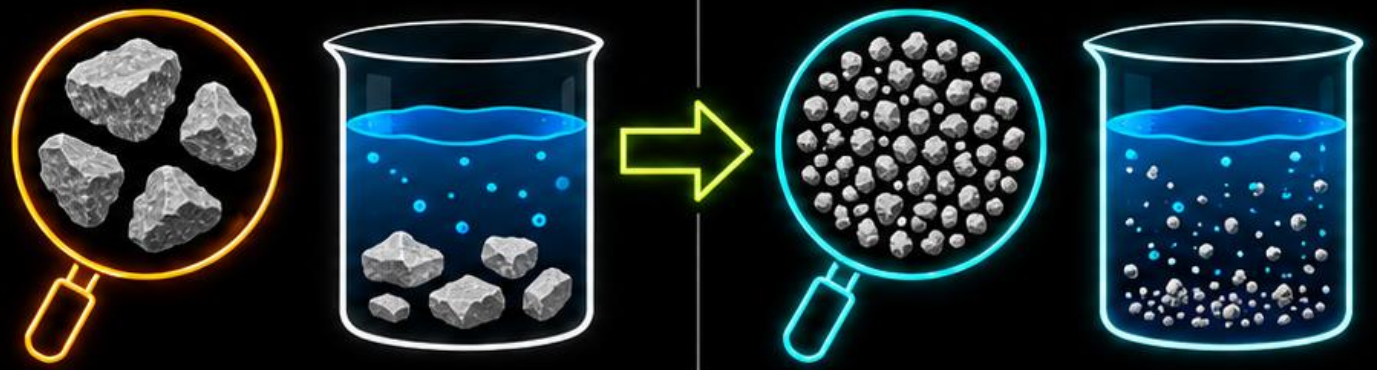
Same mass → More pieces → **More total surface**

BEFORE

Larger Particles

AFTER

Micronized Particles



SURFACE AREA INCREASES

m^2

More particles = **More total surface**

WHY IT MATTERS

- ★ More surface contact with dissolution medium
- ★ Often → **Faster dissolution**

MEMORY TRICK

Size ↓, Surface area ↑

TAKEAWAY:

Micronization **improves surface exposure** of the drug.

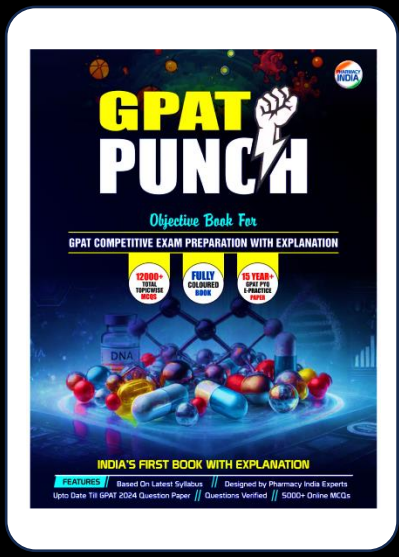
25. The ability of a substance to exist in two or more crystalline phases is:

(a) Cocrystal

(b) Crystal

(c) Polymorphism

(d) None of the above



25. The ability of a substance to exist in two or more crystalline phases is:

(a) Cocrystal

(b) Crystal

(c) Polymorphism

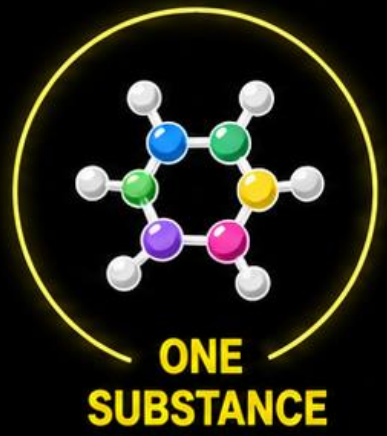
(d) None of the above

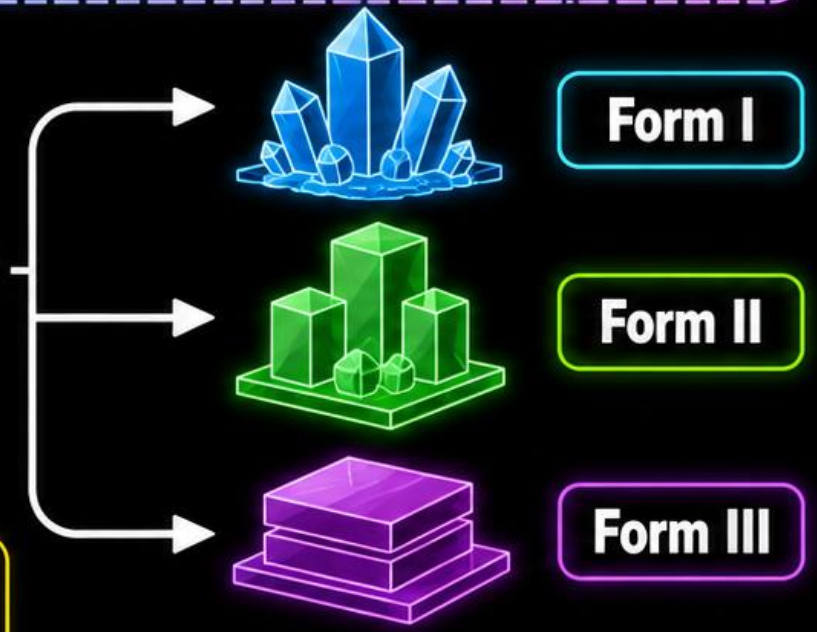
POLYMORPHISM

Correct concept

A substance existing in 2 or more crystalline phases = Polymorphism

- Same chemical substance
- Different crystal arrangement
- Different crystalline forms
- Examples: Form I, Form II, Form III





Key idea:
Chemical composition same, crystal form different

Ability to exist in two or more crystalline phases → POLYMORPHISM

26. **Which polymorphic form of riboflavin is more soluble?**

(a) Form I

(b) Form II

(c) Form III

(d) All are equal

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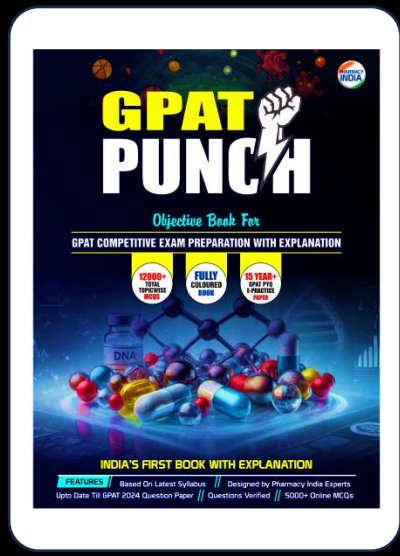
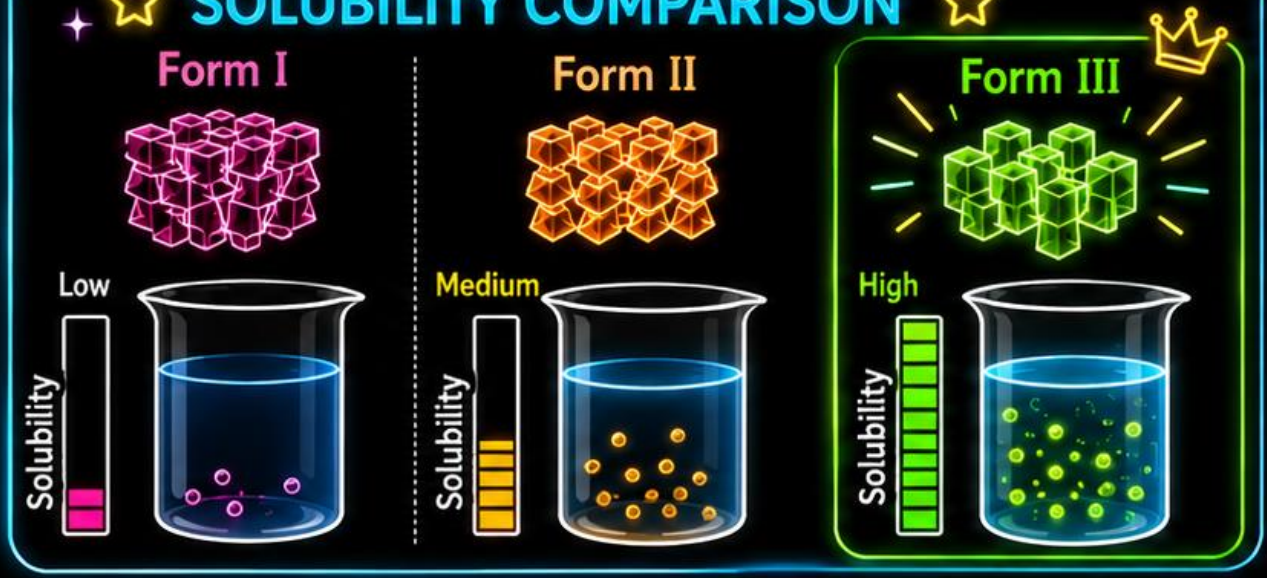


RIBOFLAVIN POLYMORPHS

MORE SOLUBLE: FORM III

Different crystal packing can change solubility.

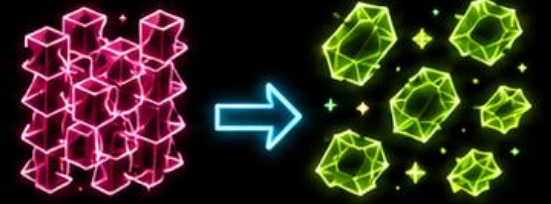
SOLUBILITY COMPARISON



KEY IDEA

- Same drug
- Different crystal form
- Physical property changes
- Form III dissolves better

WHY?



improves dissolution.

Remember: Polymorphs may differ in solubility — Riboflavin Form III is more soluble.

27. Amorphous solids are considered wrongly labeled as which of the following?

(a) Anisotropic

(b) Flowing

(c) Super cooled fluids

(d) Lacking melting point

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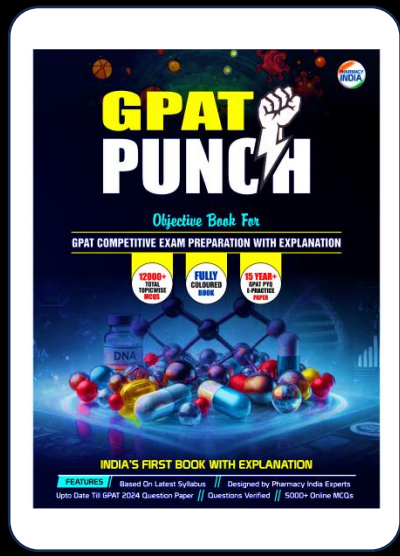


AMORPHOUS SOLIDS

⚠ Wrong label: Anisotropic

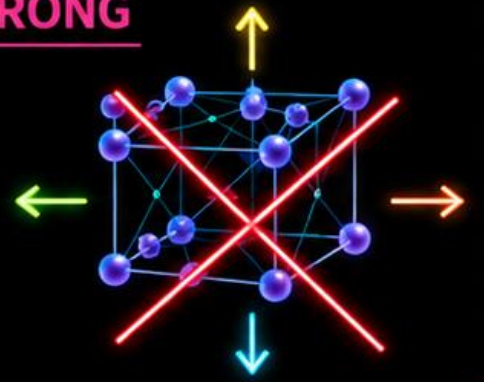
1 CORRECT CONCEPT

Amorphous solids are **ISOTROPIC.** ✓

⇨ Properties are **same** in all directions.

2 WHY ANISOTROPIC IS WRONG

Anisotropy is a property of **CRYSTALS.**

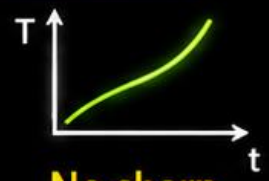


⇨ It **changes** with direction.

3 KEY FEATURES OF AMORPHOUS SOLIDS

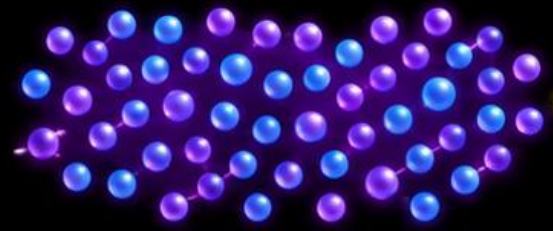
Random arrangement

Supercooled fluids



No sharp melting point

AMORPHOUS



No long-range **order**

MEMORY TRICK

Amorphous = **random** + **isotropic** ✓

TAKEAWAY

✗ Wrong label → **Anisotropic**

✓ Correct idea → **Isotropic**

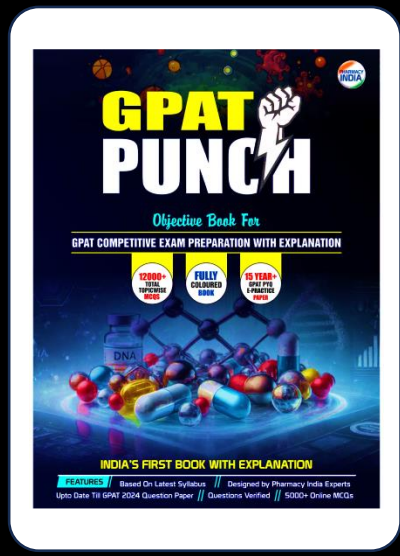
28. **Polymorphs exhibit different properties EXCEPT:**

(a) X-ray diffraction patterns

(b) Melting points

(c) Solubilities

(d) Chemical structures



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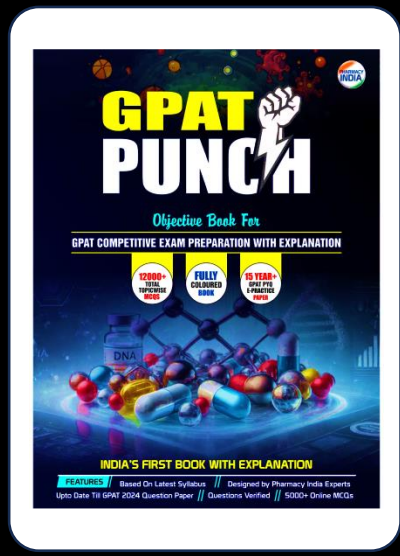
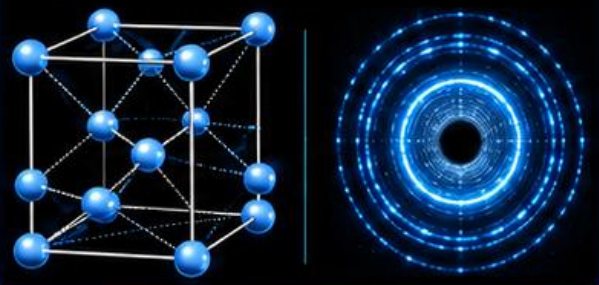


Polymorphs: Different Physical Properties, Same Chemical Structure

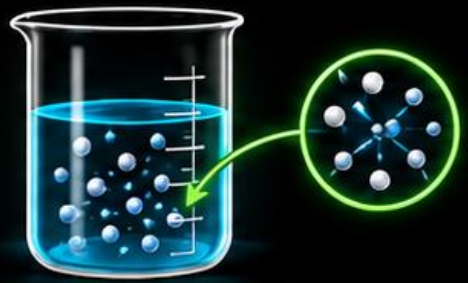
☆ **EXCEPT:** Chemical structure does **NOT** change.

1 **X-ray pattern**
- Different

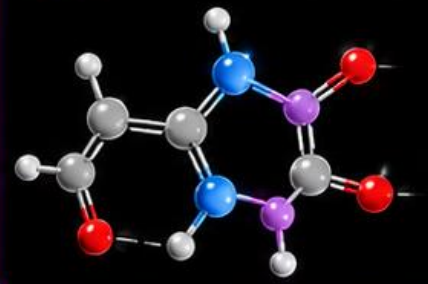


2 **Melting point**
- Different

3 **Solubility**
- Different

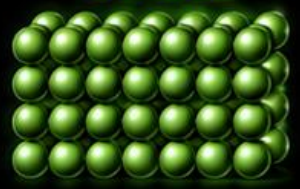


4 **Chemical structure**
- Same



SAME!

STABLE



METASTABLE

UNSTABLE

Arrangement changes, **not** the molecule.

☆ **EXAM PEARL** ☆

Polymorphs differ in **crystal arrangement**, not in **chemical identity.**

Same drug molecule → **different crystal form** → **different physical properties.**

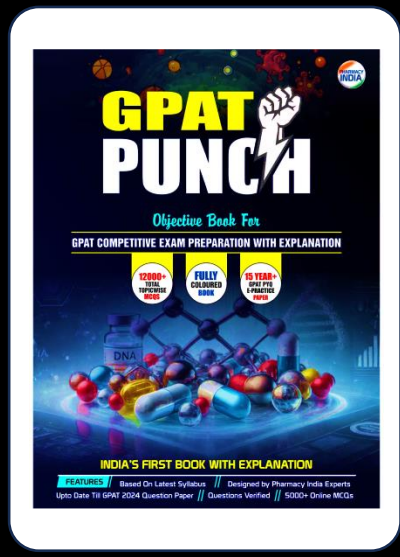
29. **The metastable polymorphic form generally results in:**

(a) Lower dissolution rate

(b) Higher dissolution rate

(c) No change

(d) Higher melting point



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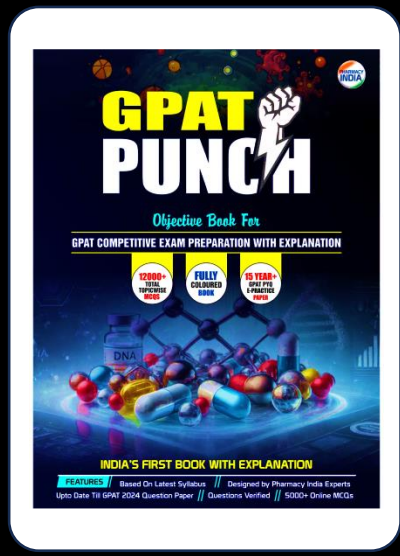


METASTABLE POLYMORPH

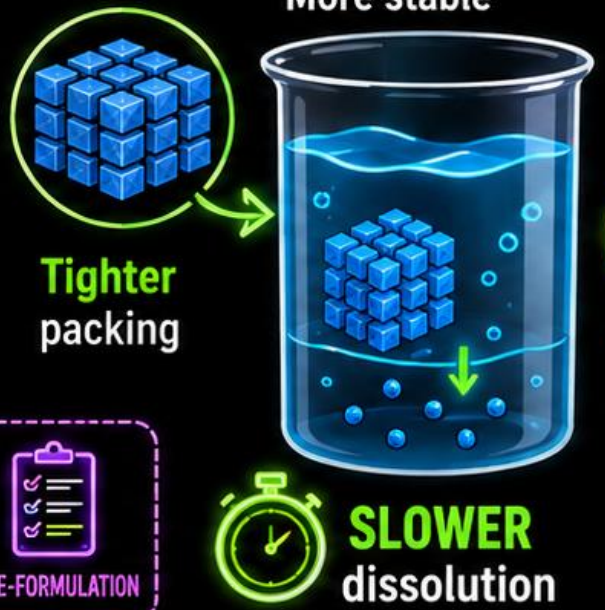
Higher dissolution rate

KEY IDEA

Metastable form is **less stable** and has **higher free energy.**

STABLE FORM

More stable



Tighter packing

SLOWER dissolution

VS

METASTABLE FORM

Less stable

Looser packing

FASTER dissolution

WHY FASTER?

- Higher **free energy**
- Lower **stability**
- Better **apparent solubility**

CRYSTAL | DISSOLUTION | MOLECULE | PRE-FORMULATION

LESS STABLE CRYSTAL → DISSOLVES FASTER

METASTABLE FORM USUALLY HAS LOWER MELTING POINT THAN STABLE FORM.

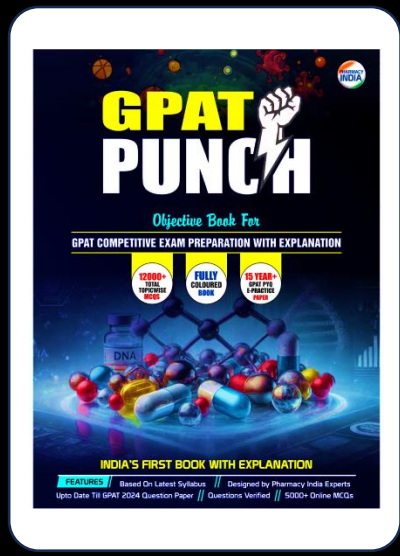
30. **Which instrument is used for particle size analysis based on laser diffraction?**

(a) Coulter Counter

(b) Royco Instrument

(c) SEM

(d) Sieving



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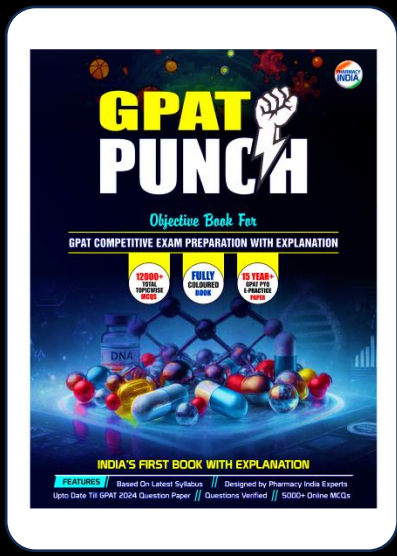


LASER DIFFRACTION

Particle Size Analysis

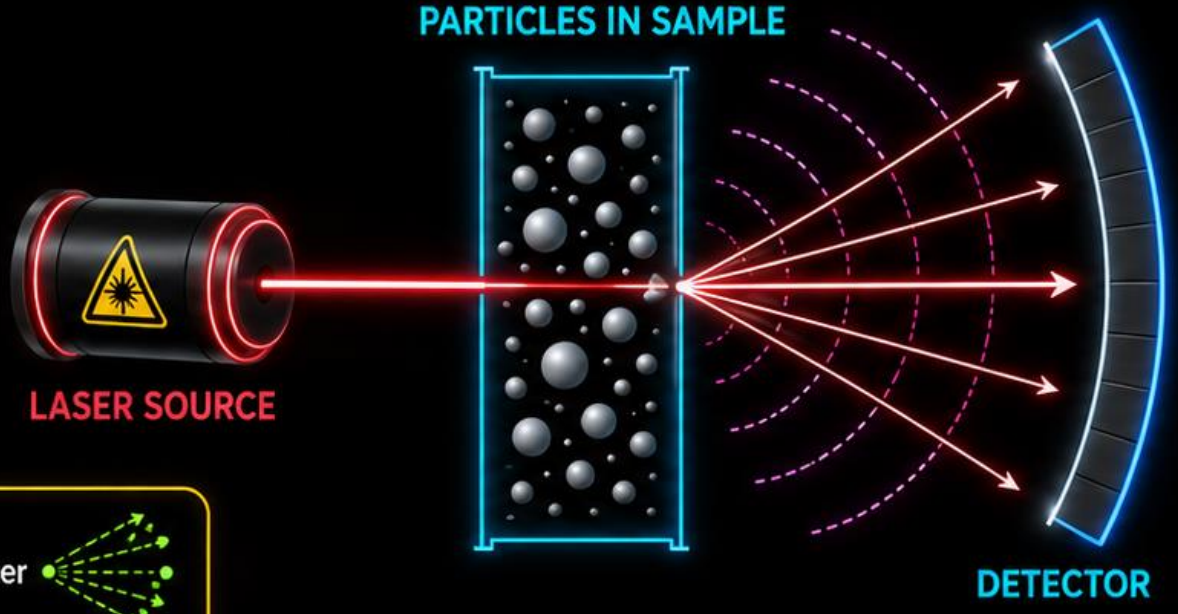
Instrument: Royco Instrument

1 WHAT IT MEASURES

Particle size distribution

2 PRINCIPLE

Laser beam + scattering pattern



3 KEY IDEA

Small particles = wide scatter

Large particles = narrow scatter

4 WHY USEFUL

FAST ACCURATE NON-DESTRUCTIVE

MEMORY LINE: Royco → Laser diffraction

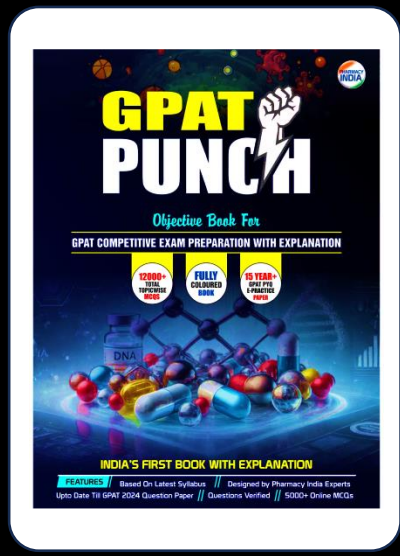
31. **An optimum level of moisture in a powder significantly influences:**

(a) Surface morphology

(b) Density

(c) Tensile strength

(d) Sedimentation



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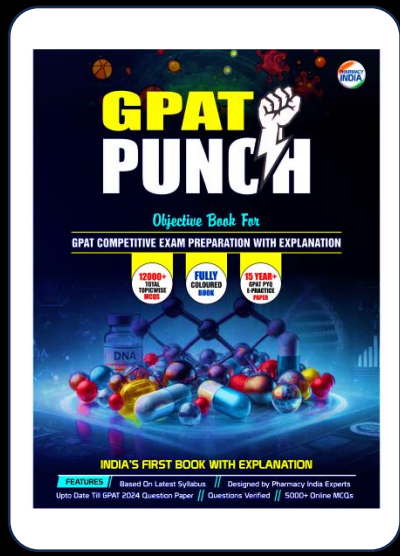
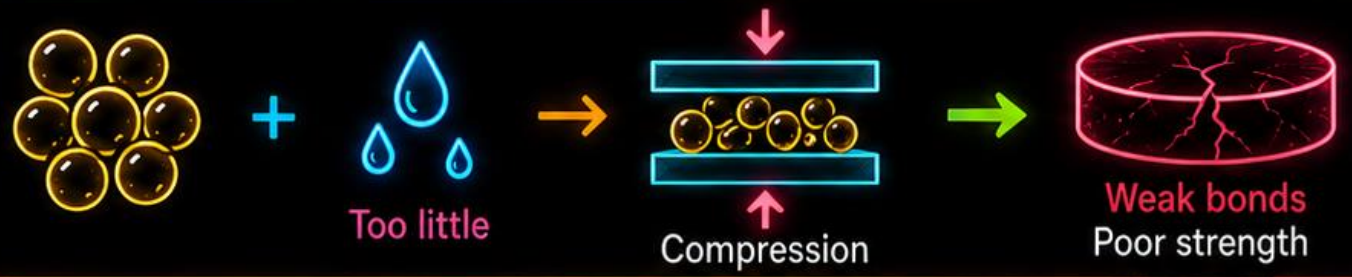


Moisture & Tensile Strength

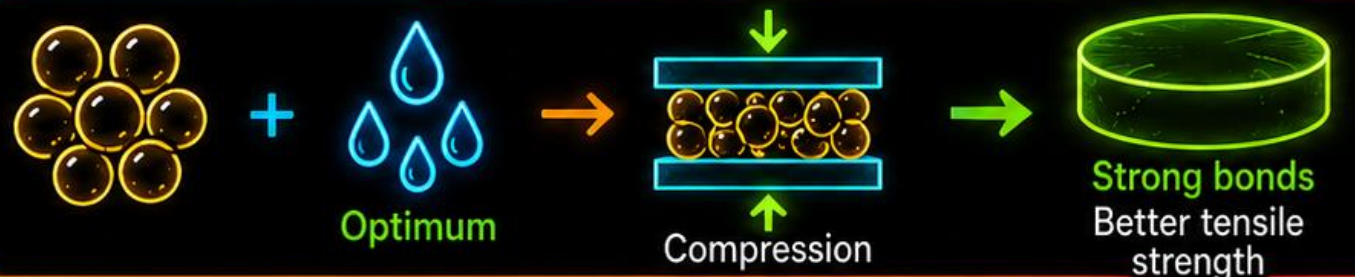
Optimum moisture improves particle bonding

1. Too low moisture

→ weak bonding

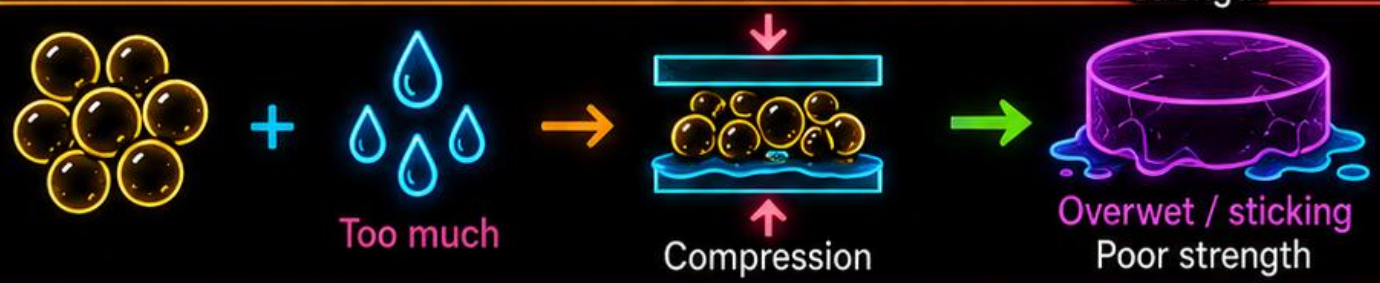


2. Optimum moisture



3. Too high moisture

→ overwet / sticking



KEY POINTS

- Moisture acts as a binder
- Improves particle plasticity
- Enhances cohesion on compression
- Best hardness at optimum level
- Excess moisture causes problems

Moisture Level → Particle Bonding → Cohesion on Compression → Tensile Strength (Hardness) → Optimum = Best Result

32. **Tapped density is calculated as:**

(a) Mass / Tapped Volume

(b) Tapped Volume / Mass

(c) Mass / Bulk Volume

(d) Volume / Density

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(a) Mass / Tapped Volume

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(c) Mass / Bulk Volume

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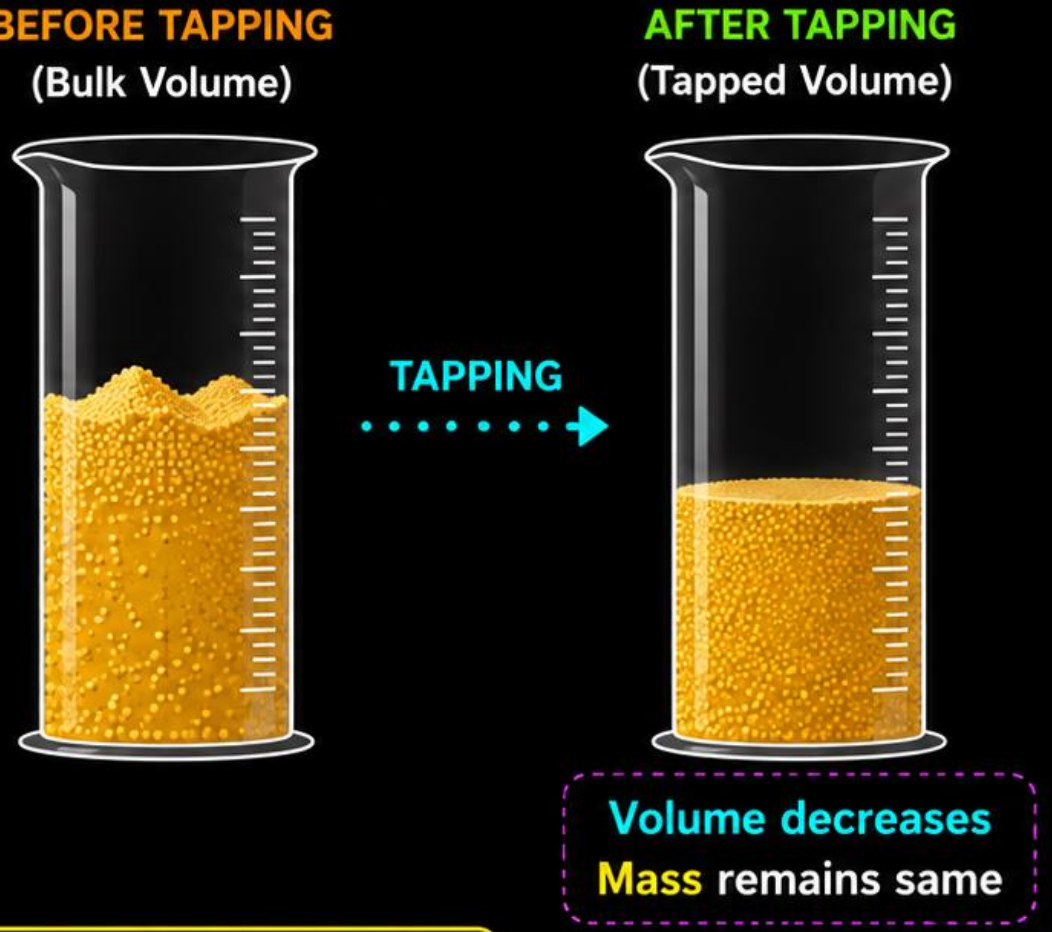
TAPPED DENSITY

★ **Tapped density** is the ratio of **mass** of powder to its **tapped volume**.

$$\text{Tapped Density} = \frac{\text{Mass of Powder}}{\text{Tapped Volume}}$$

Indicates how well powder compacts after tapping.



Higher tapped density → Better flow and compactibility.

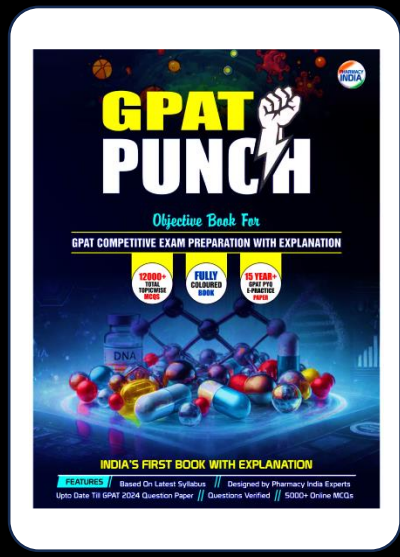
33. **Which method is used to determine the pKa of a drug?**

(a) Chromatographic method

(b) Filter probe method

(c) Foaming activity method

(d) All of the above



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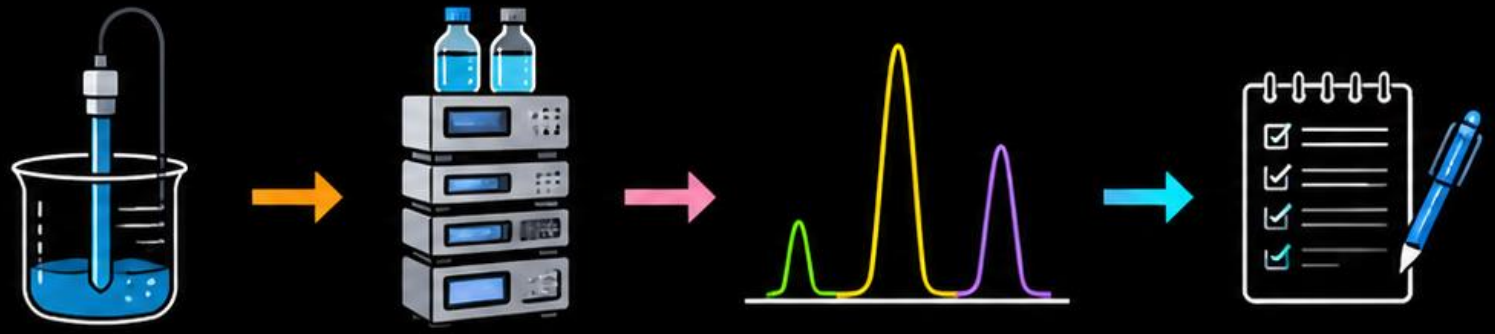
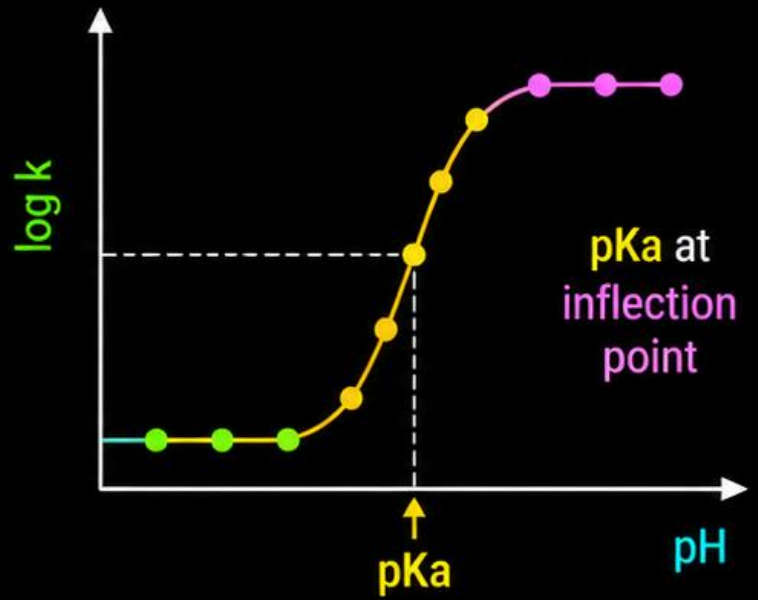
pKa of a Drug – Determined by Chromatographic Method

Principle:

Ionization of drug changes with pH → affects retention in chromatography.



1. Prepare buffers of different pH
2. Inject drug and run
3. Measure retention (k or t_R)
4. Plot log k vs pH and analyze



★ **pKa = pH at inflection point**

Why Chromatographic Method?

- Accurate
- Sensitive
- Suitable for wide range of drugs
- Reliable & Reproducible
- Standard & Widely Accepted

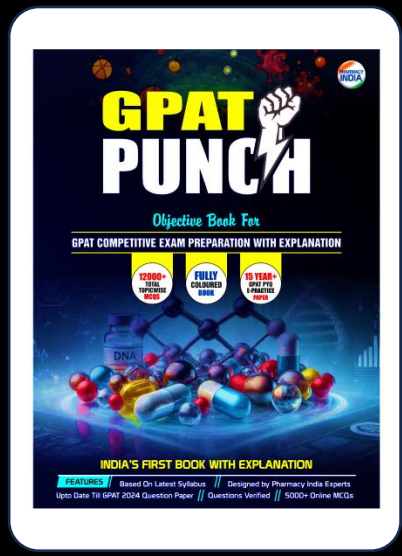
34. **Partition coefficient mainly indicates drug:**

(a) Crystal habit

(b) Lipophilicity

(c) Hygroscopicity

(d) Compressibility



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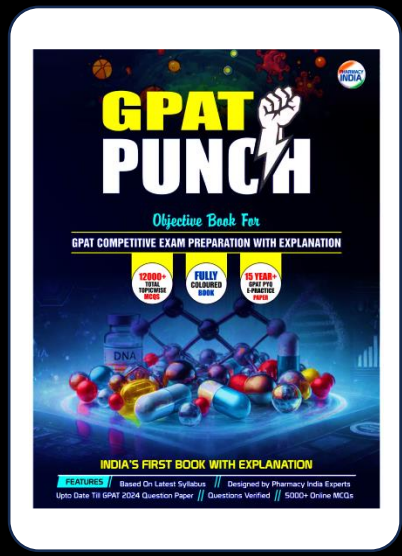


Partition Coefficient (P)

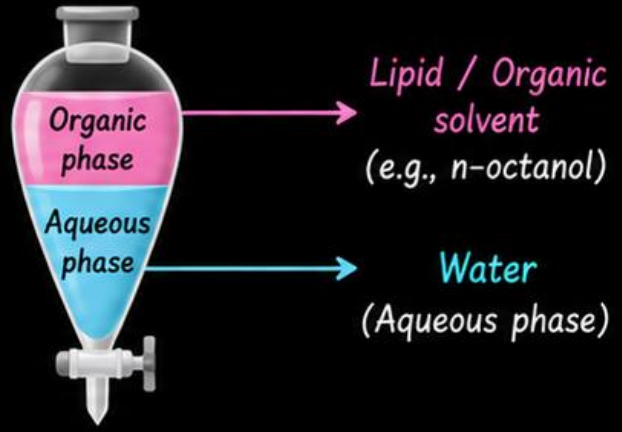
Mainly indicates drug Lipophilicity

What is Partition Coefficient?

It is the ratio of drug concentration in organic phase to that in aqueous phase at equilibrium.

$$P = \frac{\text{[Drug] in Organic phase}}{\text{[Drug] in Aqueous phase}}$$

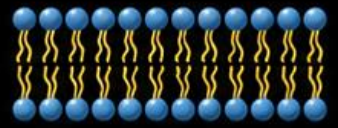
Drug between two immiscible solvents at equilibrium



What does P indicate?

- High P (> 1) → More in organic phase (More lipophilic)
- P ≈ 1 → Equal in both phases (Moderate lipophilicity)
- Low P (< 1) → More in aqueous phase (Less lipophilic)

How it relates to Lipophilicity?



Lipophilic drugs prefer lipid (organic phase)

→ Easier to cross biological membranes

→ Better absorption & distribution

Key Point

Higher partition coefficient = Higher lipophilicity

Lower partition coefficient = Lower lipophilicity

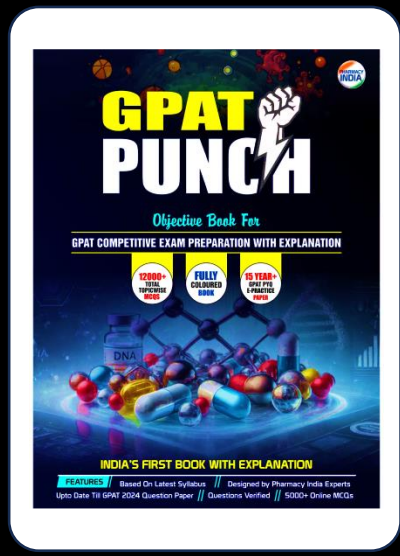
35. **The point where pH = pKa is known as the:**

(a) Neutralization point

(b) Equivalence point

(c) Half-neutralization point

(d) End point



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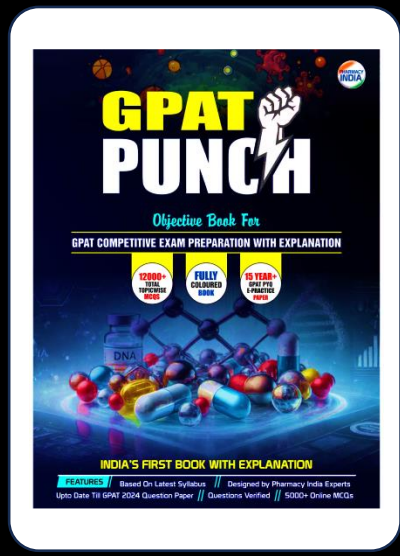


pH = pKa

Occurs at Half-neutralization point

At this point:

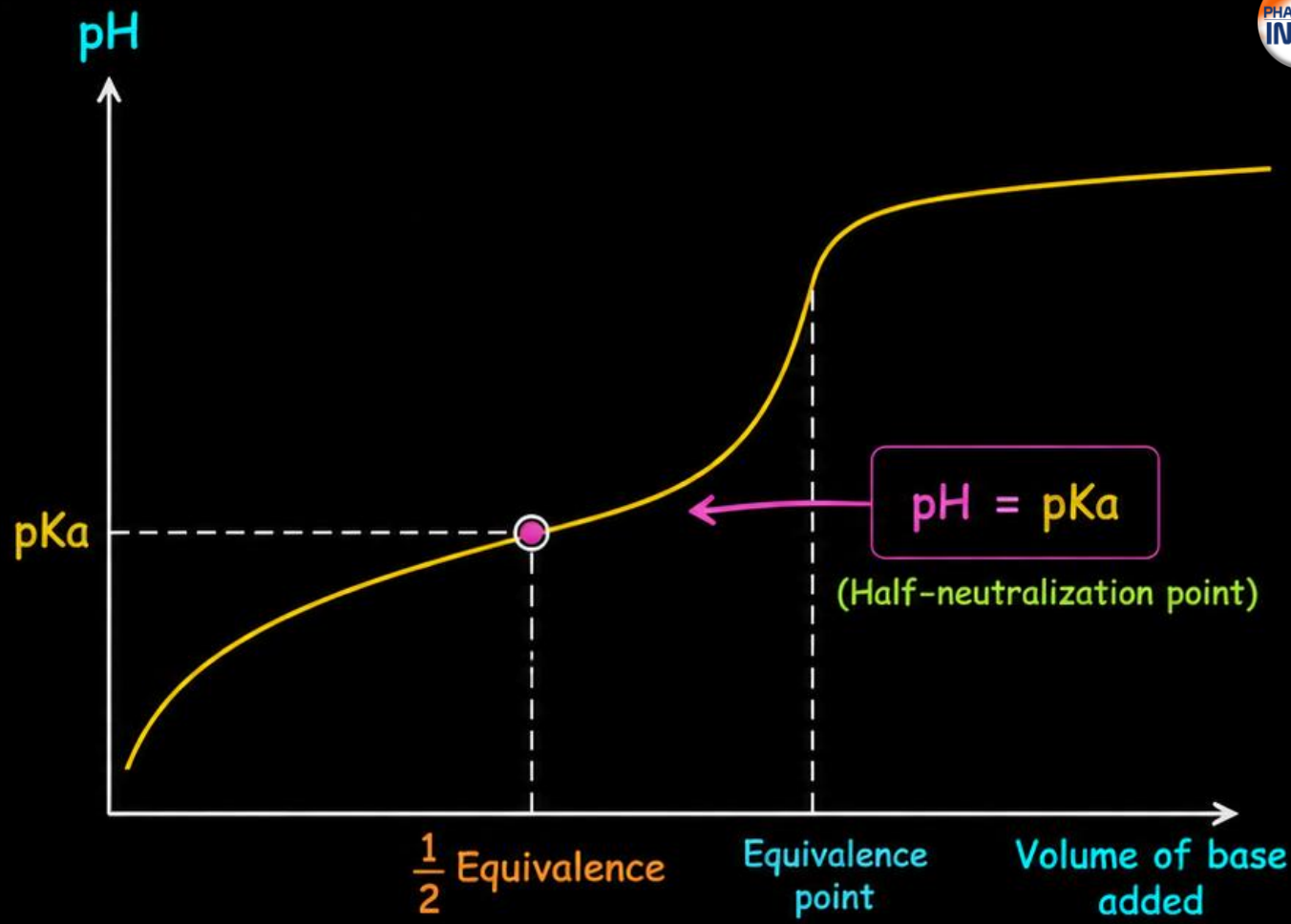
$[HA] = [A^-]$

From Henderson-Hasselbalch equation

$$pH = pKa + \log \frac{[A^-]}{[HA]}$$

When $[A^-] = [HA] \rightarrow \log 1 = 0$

$\therefore$ pH = pKa



pH = pKa indicates equal concentrations of acid and conjugate base.

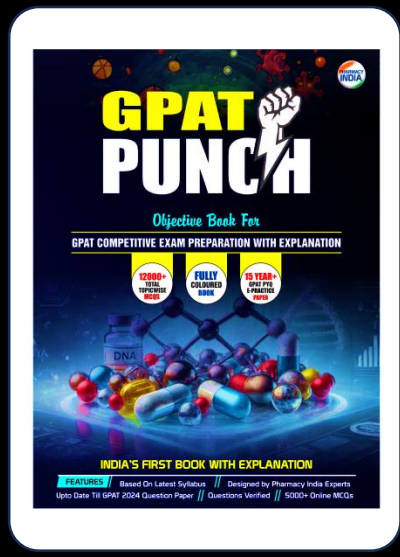
36. Which equation is used to determine the dissociation constant (pKa) of a drug?

(a) Noyes-Whitney

(b) Arrhenius

(c) Henderson-Hasselbalch

(d) Stokes Law



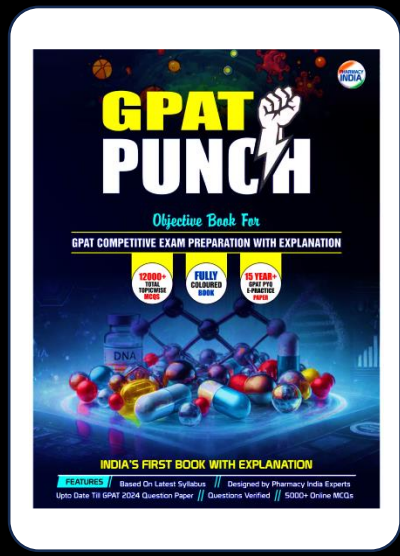
36. Which equation is used to determine the dissociation constant (pKa) of a drug?

(a) Noyes-Whitney

(b) Arrhenius

(c) Henderson-Hasselbalch

(d) Stokes Law



Dissociation Constant (pKa) of a Drug

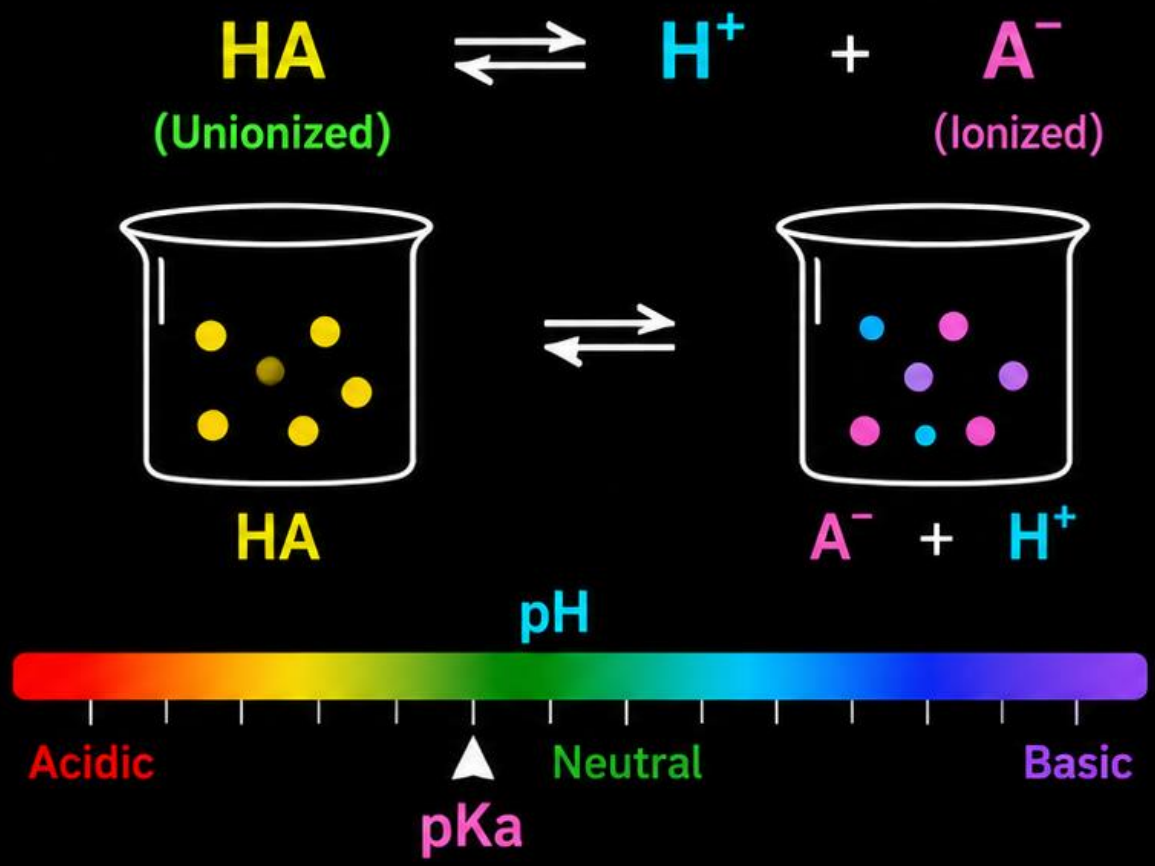
Key Point:

pKa is determined using the **Henderson–Hasselbalch equation**, which relates pH, pKa and ionization.

Henderson–Hasselbalch Equation

$$pH = pKa + \log \frac{[A^-]}{[HA]}$$

- $[HA]$ = Concentration of unionized drug (acid form)
- $[A^-]$ = Concentration of ionized drug (base/anion form)
- pKa = pH at which $[HA] = [A^-]$ (50% ionized)



Used to find pKa from pH and ionization data.

Essential for drug **absorption, distribution** and **ionization** behavior.

Henderson–Hasselbalch is the standard equation for **pKa** determination.

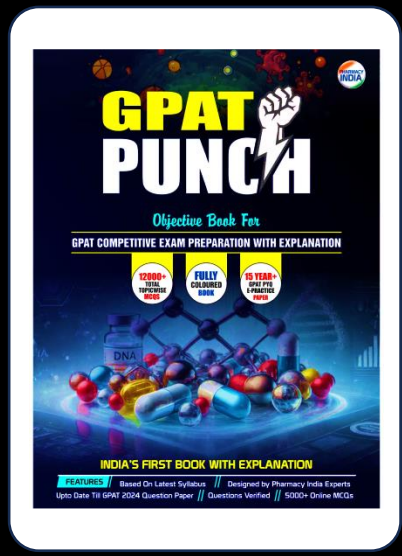
37. **The extent of ionization of a weak electrolyte drug depends on:**

(a) Particle size

(b) Dissolution rate

(c) pH of media and pKa

(d) Surface area



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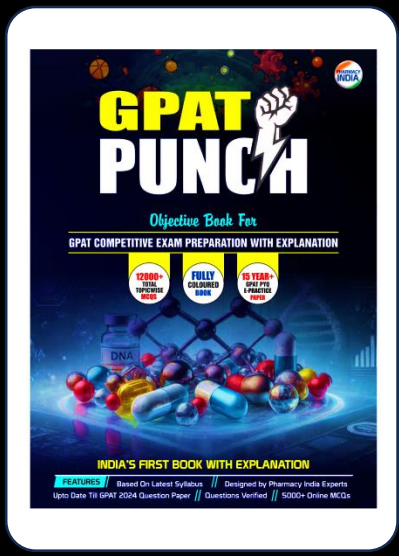
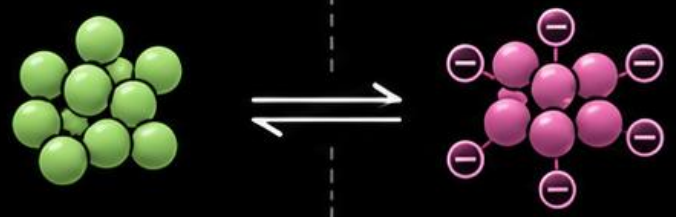


Extent of Ionization of a Weak Electrolyte Drug

Depends on: pH of media and pKa

Weak Electrolyte Drug

Unionized form (HA) ⇌ Ionized form (A^-)



Lipid soluble (More absorption) — Water soluble (Less absorption)

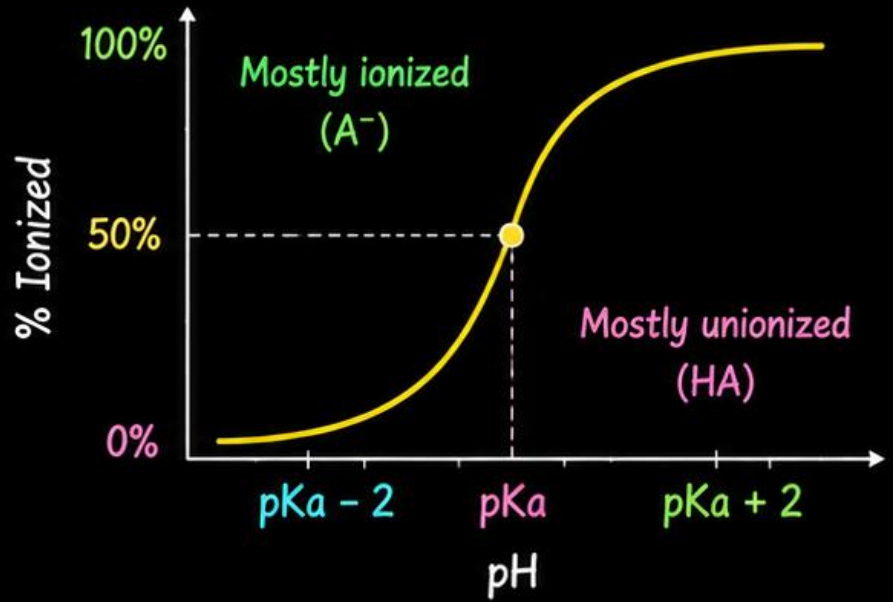
Ionization depends on pH and pKa

Henderson–Hasselbalch equation

$$pH = pKa + \log \frac{[A^-]}{[HA]}$$

- pH of the media
- pKa of the drug

Effect of pH (vs pKa)



Key Point

- Ionization ↑ with ↑ pH (for weak acids)
- Ionization ↓ with ↓ pH (for weak acids)
- pH & pKa control ionization & absorption

38. **Crystal habit refers to the:**

(a) Internal structure

(b) External shape

(c) Density

(d) Purity

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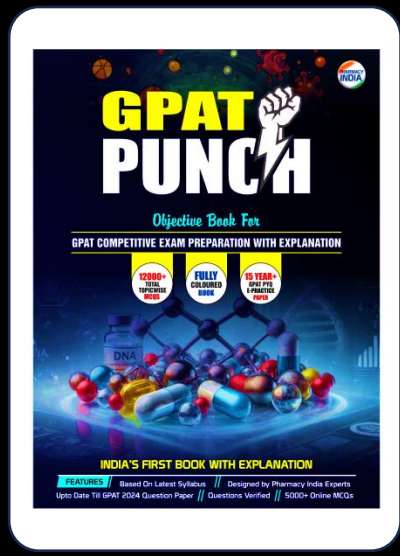

Crystal Habit

Crystal habit refers to the **external shape** of a crystal.

It describes how a crystal **looks** from the **outside.**

Same substance, different habits

39. **Solvates are also known as pseudopolymorphs because they have:**

(a) Identical chemical structures

(b) Trapped solvent in the lattice

(c) No crystalline order

(d) Mirror image structures

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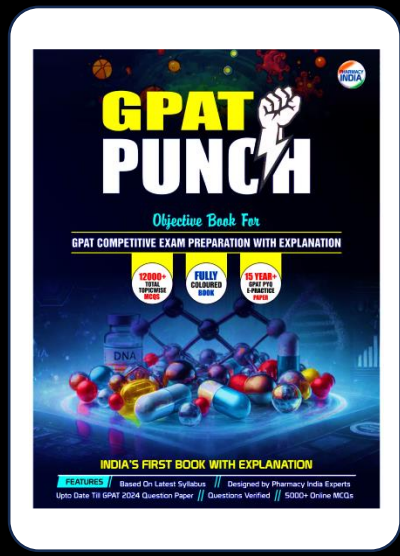
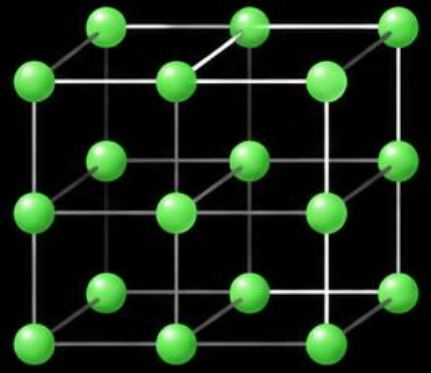


Why Solvates are called Pseudopolymorphs?

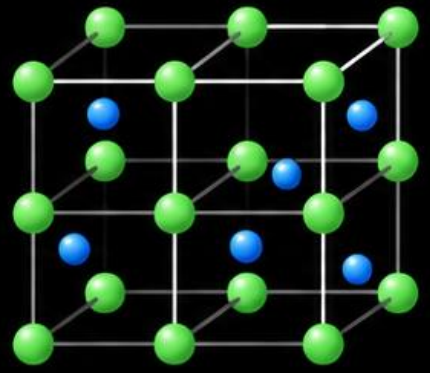
Solvates are **pseudopolymorphs** because they contain **trapped solvent molecules** in the **crystal lattice**.

Anhydrous Form



Only drug molecules in the lattice

Solvate Form



Solvent molecules trapped in the lattice

- Drug molecule
- Solvent molecule (trapped)

Same chemical entity, different crystal forms due to **trapped solvent**.

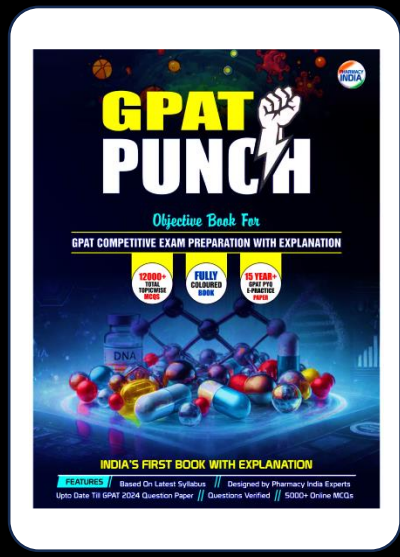
40. **Which of the following is a limitation of the Henderson-Hasselbalch equation?**

(a) It predicts solubility

(b) It fails outside the pH range of 4 to 10

(c) It determines pKa

(d) It calculates percent ionization



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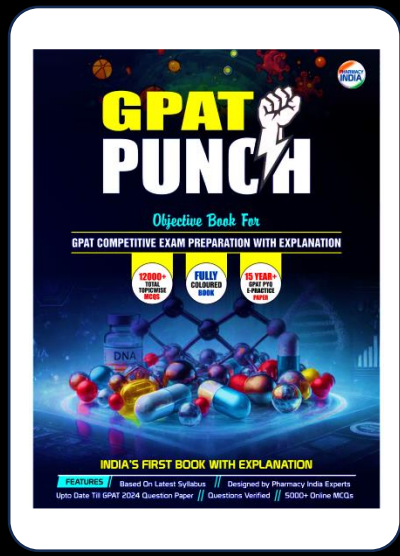


Limitation of Henderson-Hasselbalch Equation

Fails outside the pH range of 4 to 10

$$pH = pKa + \log \frac{[A^-]}{[HA]}$$

Reliable when

$0.1 \leq [A^-]/[HA] \leq 10$

↓

pH within ~ pKa ± 1

⇒ roughly pH 4 to 10

⚠ Outside pH 4 to 10

pH < 4

→ $[A^-]$ very small → Inaccurate

pH > 10

→ [HA] very small → Inaccurate

Best accuracy when pH is within 4 to 10 (≈ pKa ± 1)

41. For a poorly soluble drug, the most important preformulation study is:

(a) Particle size analysis

(b) Microbial testing

(c) Viscosity measurement

(d) Color stability

41. For a poorly soluble drug, the most important preformulation study is:

(a) Particle size analysis

(b) Microbial testing

(c) Viscosity measurement

(d) Color stability

★ EXPLANATION ★

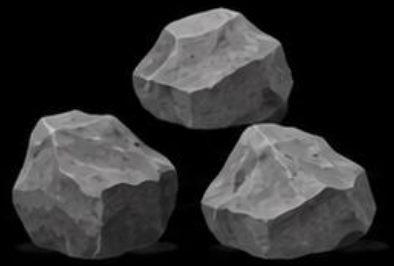
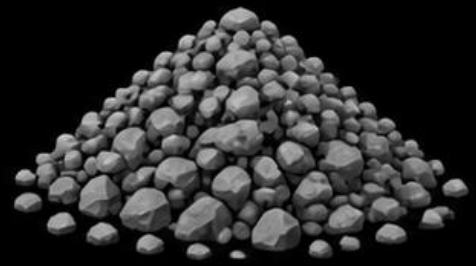
For a *poorly soluble drug*, the most important preformulation study is ***Particle size analysis***.

Smaller particle size
→ Increases surface area

Higher surface area
→ Improves dissolution rate

Better dissolution
→ Enhanced bioavailability

★ **Particle size** directly impacts **dissolution** and **absorption** of poorly soluble drugs.

LARGE PARTICLE SIZE	SMALL PARTICLE SIZE
	
Low surface area	High surface area
↓	↓
Poor dissolution	Good dissolution
	

★ **Smaller** particles = **Better** performance

42. Which technique is used to determine the surface area of particles?

(a) Coulter Counter

(b) BET Nitrogen Adsorption

(c) SEM

(d) XRD

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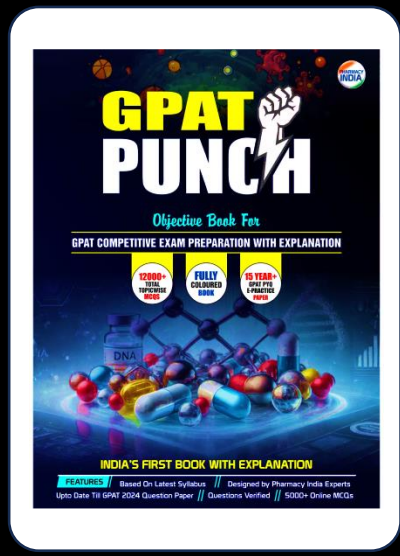


Surface Area of Particles

Technique Used: BET Nitrogen Adsorption

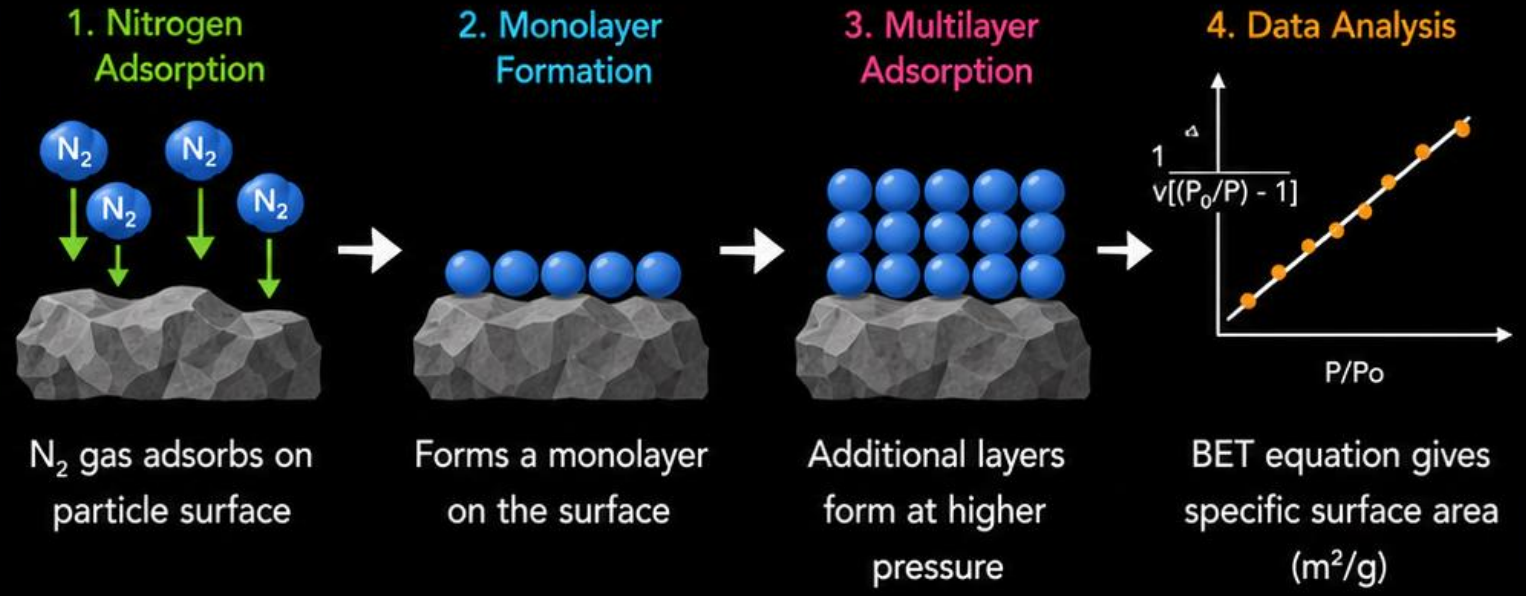
Why BET?

BET (Brunauer–Emmett–Teller) measures the specific surface area by physical adsorption of nitrogen gas.

How it works

- Nitrogen gas adsorbs on particle surfaces at cryogenic temperature (-196°C).
- Amount adsorbed is measured at different pressures.
- BET equation is applied to calculate surface area.
- Reported as m^2/g.

BET Principle



N_2 gas adsorbs on particle surface

Forms a monolayer on the surface

Additional layers form at higher pressure

BET equation gives specific surface area (m^2/g)

Why other options are not used?

- ✗ Coulter Counter – Measures particle size distribution.
- ✗ SEM – Gives surface morphology, not surface area.
- ✗ XRD – Determines crystalline structure.

BET Nitrogen Adsorption is the standard technique to determine surface area of particles.

43. **A drug with very high log P generally shows:**

(a) Poor membrane permeability

(b) Poor aqueous solubility

(c) High ionization

(d) High hygroscopicity

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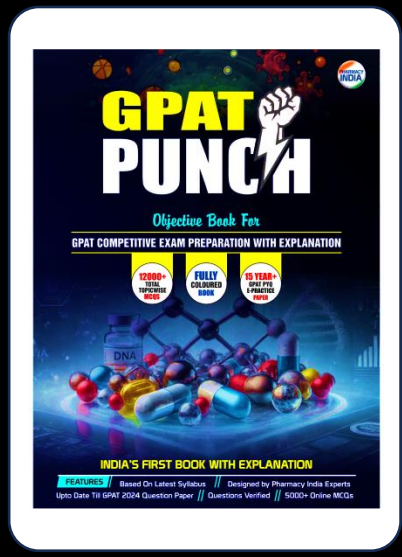


HIGH LOG P → POOR AQUEOUS SOLUBILITY

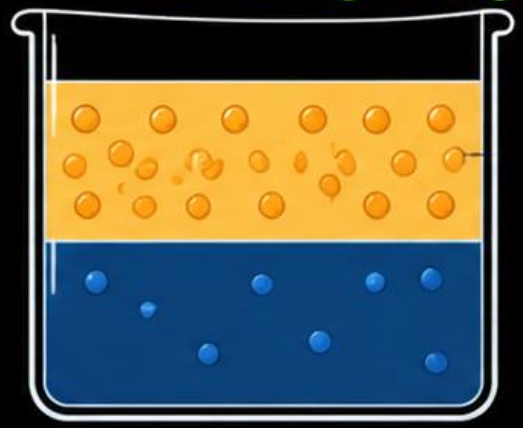
Log P is the log of the partition coefficient between octanol (lipid) and water.

$$\log P = \log \left[\frac{[\text{Drug}]_{\text{octanol}}}{[\text{Drug}]_{\text{water}}} \right]$$

Implication

Very high log P
↓
Drug is more lipophilic
↓
Less soluble in water
↓
Poor aqueous solubility

Partitioning of Drug



Octanol (lipid)

Water (aqueous)

High log P → More drug in octanol
Less drug in water → Poor solubility

Effect of Log P on Solubility

Log P (approx.)	Aqueous Solubility
< 0	High
0 – 3	Moderate
> 3	Low / Poor

As log P increases, aqueous solubility decreases.

Key Takeaway: A drug with very high log P is poorly soluble in water.

44. **Which of the following is NOT a property of amorphous solids?**

(a) Isotropic

(b) Higher solubility than crystals

(c) Sharp melting point

(d) Super cooled fluids

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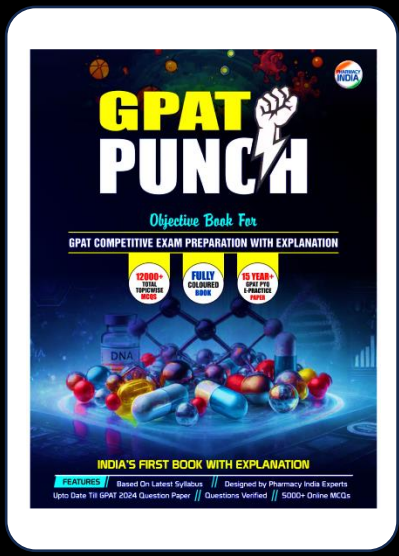


WHY SHARP MELTING POINT IS NOT A PROPERTY OF AMORPHOUS SOLIDS

PROPERTIES OF AMORPHOUS SOLIDS

Isotropic
Same properties in all directions.

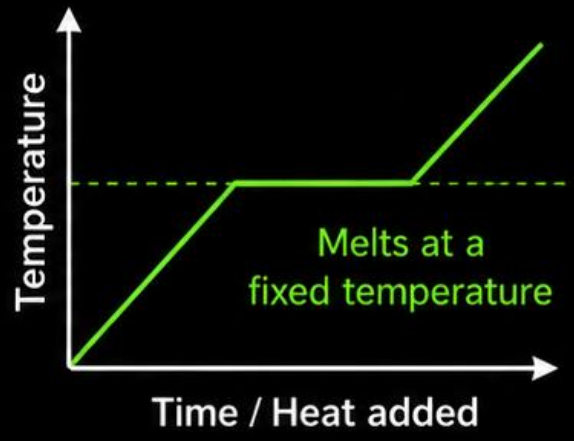
Higher solubility
Amorphous solids dissolve faster than crystals.

Super cooled fluids
Behave like super cooled liquids.

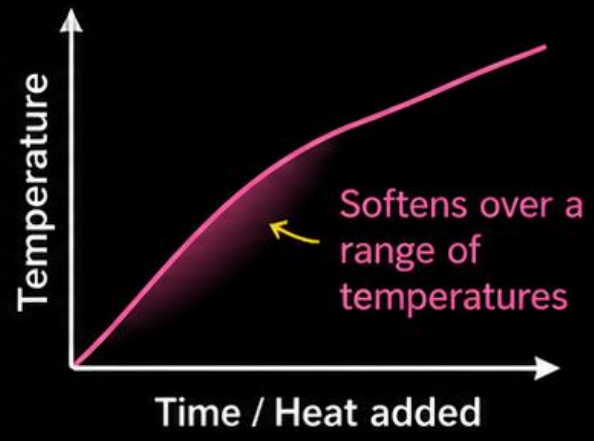
Amorphous solids **soften over a range of temperatures**, not at a sharp point.

MELTING BEHAVIOR COMPARISON

CRYSTALLINE SOLID
Sharp melting point



AMORPHOUS SOLID
No sharp melting point



Therefore, sharp melting point is **NOT** a property of amorphous solids.

45. A substance that absorbs enough moisture from the air to dissolve is:

(a) Efflorescent

(b) Deliquescent

(c) Hygroscopic

(d) Eutectic

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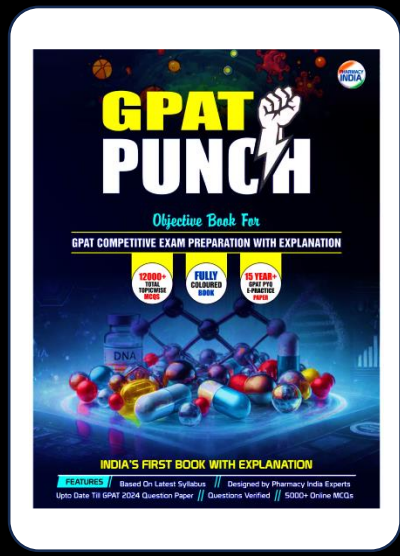

Deliquescent vs Related Terms

Deliquescent: A substance that absorbs enough moisture from the air to dissolve.

Efflorescent

Loses water of crystallization in dry air.

Example:
$Na_2CO_3 \cdot 10H_2O$

Hygroscopic

Absorbs moisture from air but does not dissolve.

Example:
$CaCl_2$ (anhydrous)

Deliquescent

Absorbs moisture from air and dissolves.

Example:
$CaCl_2$, NaOH, KOH

Eutectic

Mixture of substances that melts at a lower temperature.

Example:
Ice + NaCl

Deliquescent = Absorbs enough moisture from air to dissolve.

46. **The solubility of different forms follows the order:**

(a) Amorphous > Metastable > Stable

(b) Stable > Metastable > Amorphous

(c) Metastable > Amorphous > Stable

(d) All are equal

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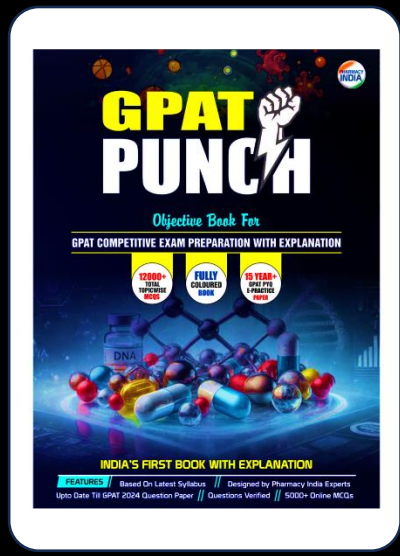


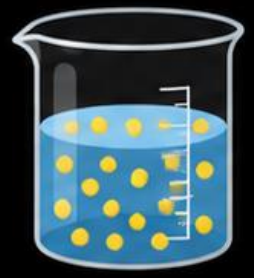
Solubility Order of Different Forms

Amorphous > Metastable > Stable

Amorphous

Disordered structure

Highest energy



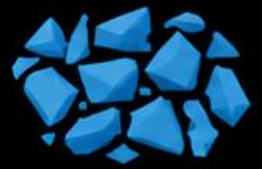
Highest solubility

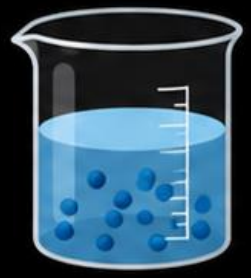
★★★★★

Metastable

Less ordered structure

Intermediate energy





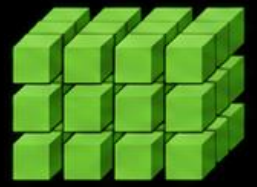
Intermediate solubility

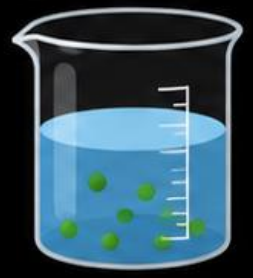
★★★

Stable

Highly ordered structure

Lowest energy





Lowest solubility

★

Why this order?

- Amorphous → highest energy, more interactions with solvent → highest solubility.
- Metastable → intermediate energy and solubility.
- Stable → lowest energy, tightly packed → lowest solubility.

Final Order:

Amorphous > Metastable > Stable

Solubility decreases as stability increases.

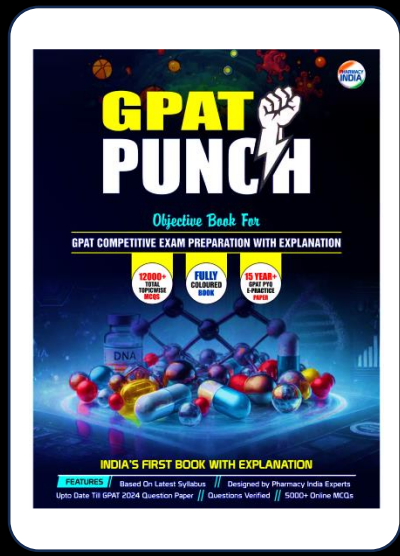
47. Which technique is most useful for identifying the degree of crystallinity?

(a) DSC

(b) SEM

(c) PXRD

(d) HPLC



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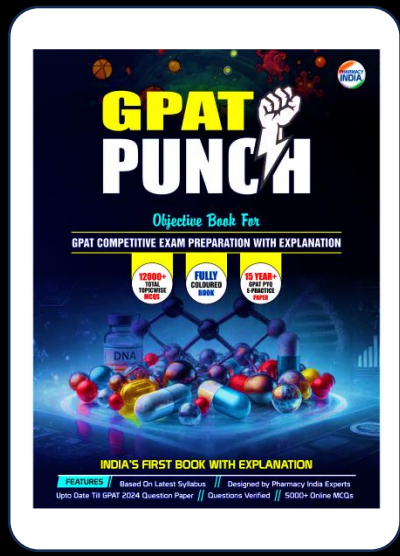


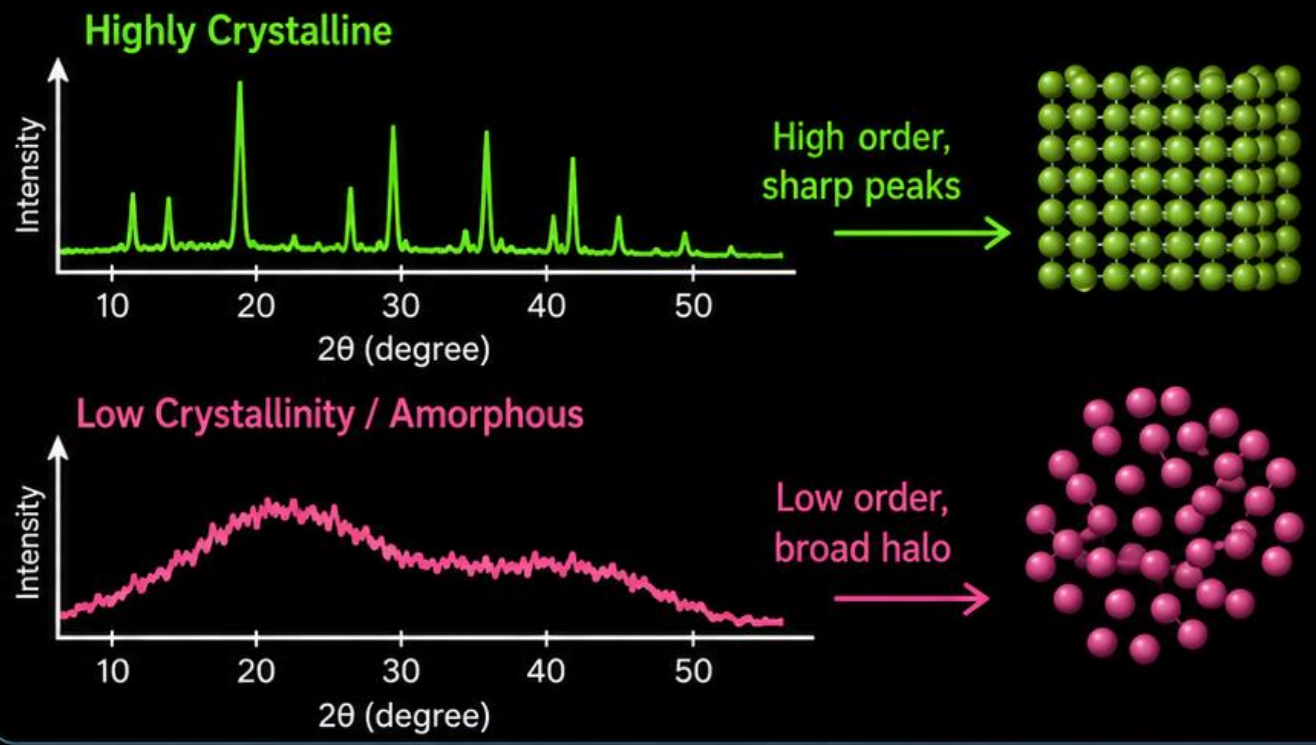
Identifying the Degree of Crystallinity

Most Useful Technique:
PXRD (Powder X-Ray Diffraction)

Why PXRD?

- Distinguishes crystalline and amorphous phases
- Peak intensity reflects degree of crystallinity
- Quantitative analysis possible (e.g., % crystallinity)

PXRD Pattern



Why Other Techniques Are Less Suitable

DSC
Measures thermal transitions, not crystal structure.

SEM
Shows surface morphology, not crystallinity.

HPLC
Used for chemical separation, not crystallinity.

PXRD is the standard and most powerful technique for determining the degree of crystallinity.

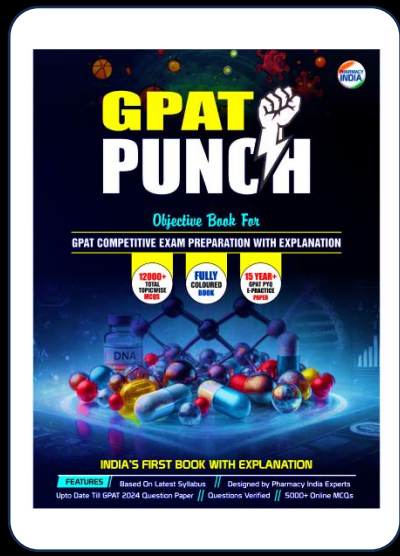
48. **DSC thermogram mainly provides information about:**

(a) UV absorbance

(b) Thermal transitions

(c) Microbial load

(d) Particle count



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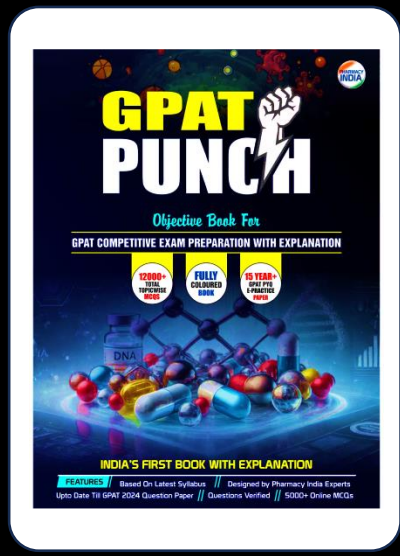
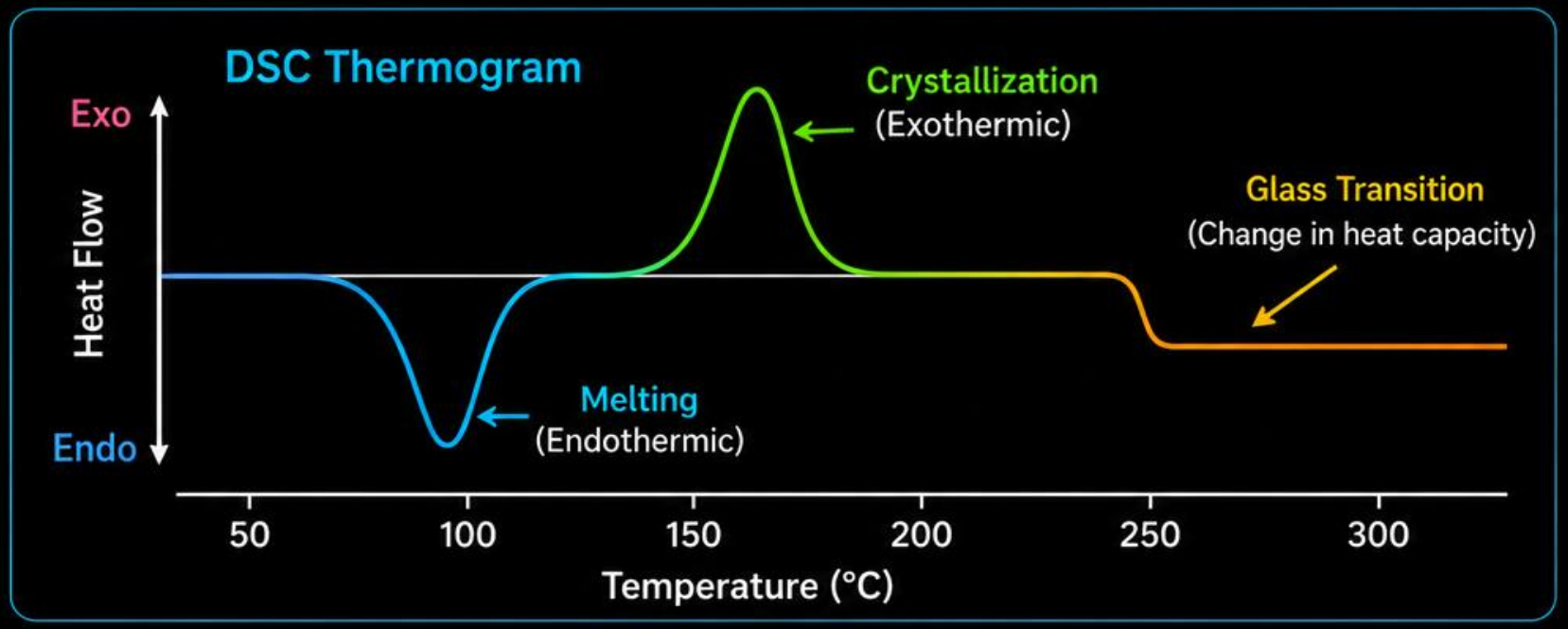


DSC thermogram mainly provides information about:

Thermal Transitions
(melting, crystallization, glass transition, etc.)

DSC Principle:
Measures heat flow associated with thermal events as a function of temperature or time.



Thermal Transitions Detected

- **Melting** (Endothermic)
  e.g., solid ⟶ liquid
- **Crystallization** (Exothermic)
  e.g., liquid ⟶ solid
- **Glass Transition (Tg)**
  e.g., amorphous polymers
- **Decomposition**
  e.g., mass loss events

Why other options are incorrect:

- **UV absorbance**
  Measured by UV-Vis spectroscopy, not DSC.
- **Microbial load**
  Measured by microbiological methods, not DSC.
- **Particle count**
  Measured by particle analyzers, not DSC.

DSC is the most powerful technique to study thermal behavior and transitions in a material.

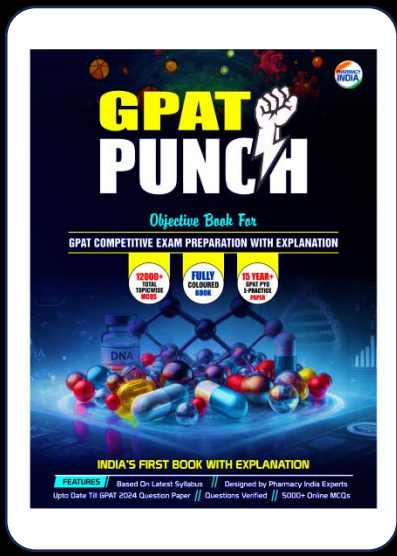
49. **Preformulation stability under acidic and alkaline conditions helps identify:**

(a) Hydrolytic degradation tendency

(b) Powder flow

(c) Crystal habit

(d) True density



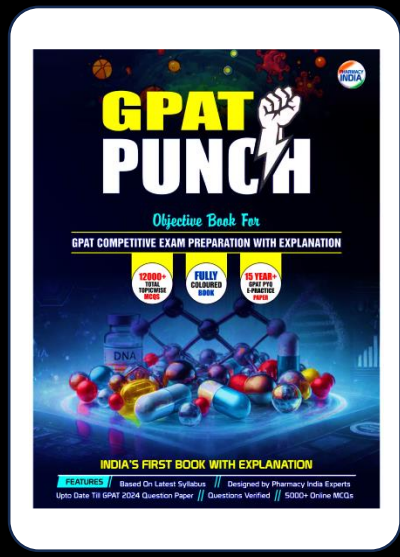
49. Preformulation stability under acidic and alkaline conditions helps identify:

(a) Hydrolytic degradation tendency

(b) Powder flow

(c) Crystal habit

(d) True density



Preformulation Stability Under Acidic & Alkaline Conditions – What Does It Help Identify?

Preformulation stability studies in acidic and alkaline media help assess the drug's chemical stability.

Acidic Condition
(e.g., 0.1 N HCl)

Drug may break down if hydrolytically unstable

Helps identify
Hydrolytic Degradation Tendency

Alkaline Condition
(e.g., 0.1 N NaOH)

Drug may break down if hydrolytically unstable

Therefore, preformulation stability under acidic and alkaline conditions helps identify hydrolytic degradation tendency.

Answer:
(a) Hydrolytic degradation tendency

50. **Which of the following is NOT a preformulation parameter?**

(a) pKa

(b) Particle size

(c) Clinical trial data

(d) Partition coefficient

50. Which of the following is NOT a preformulation parameter?

(a) pKa

(b) Particle size

(c) Clinical trial data

(d) Partition coefficient

What is NOT a Preformulation Parameter?

Preformulation studies evaluate **physicochemical properties** of a drug to develop a **safe**, **effective** and **stable** dosage form.

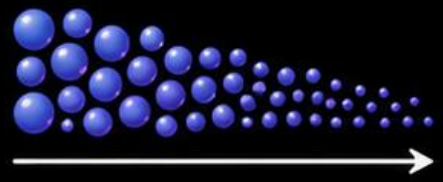
pKa

$HA \rightleftharpoons H^+ + A^-$

pKa = pH at which ionization is 50%

Helps in understanding ionization & solubility

Particle size



Affects dissolution rate, bioavailability & stability

Important preformulation parameter

Partition coefficient

$$P = \frac{C_{oil}}{C_{water}}$$

Indicates lipophilicity, affects absorption

Important preformulation parameter

Clinical trial data ✗

Generated in humans during clinical trials

NOT a preformulation parameter

Preformulation focuses on **drug** & **formulation** properties, not on **human clinical trial outcomes**.

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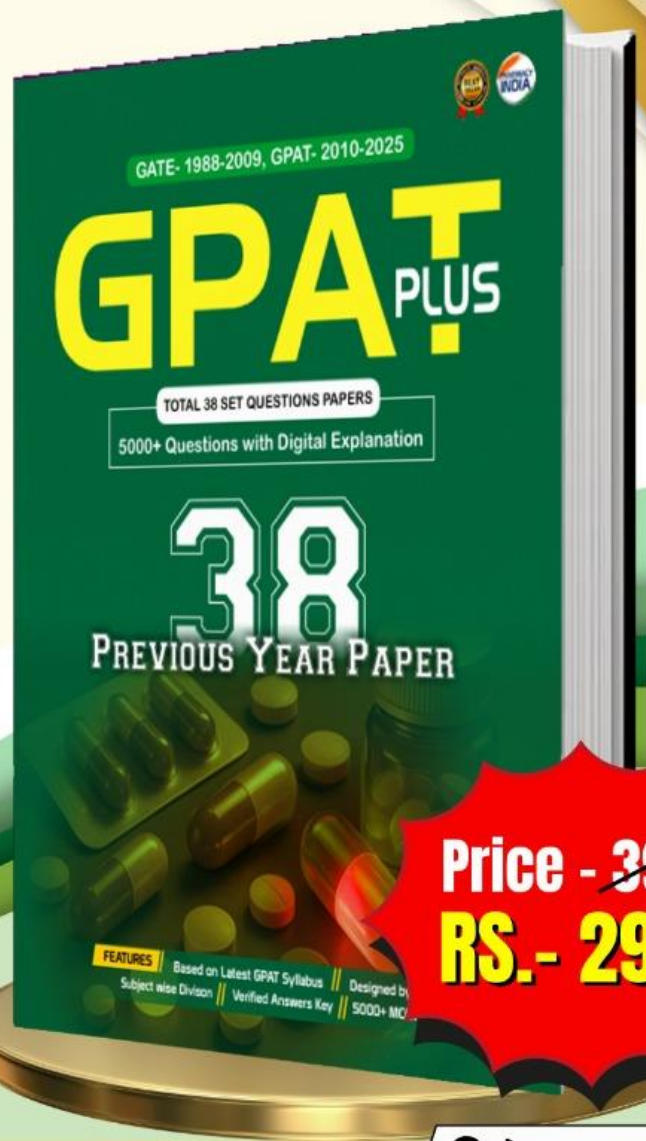

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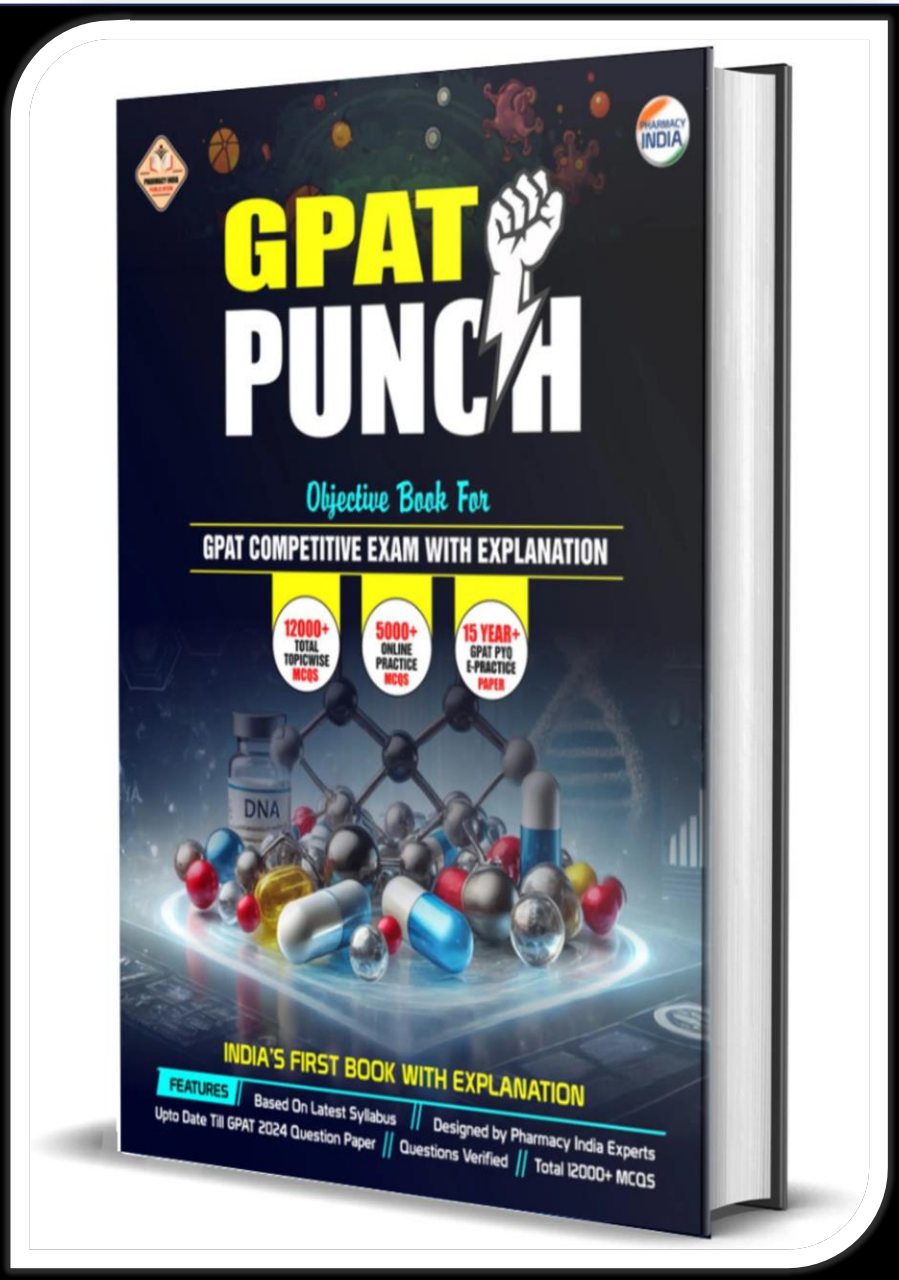

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