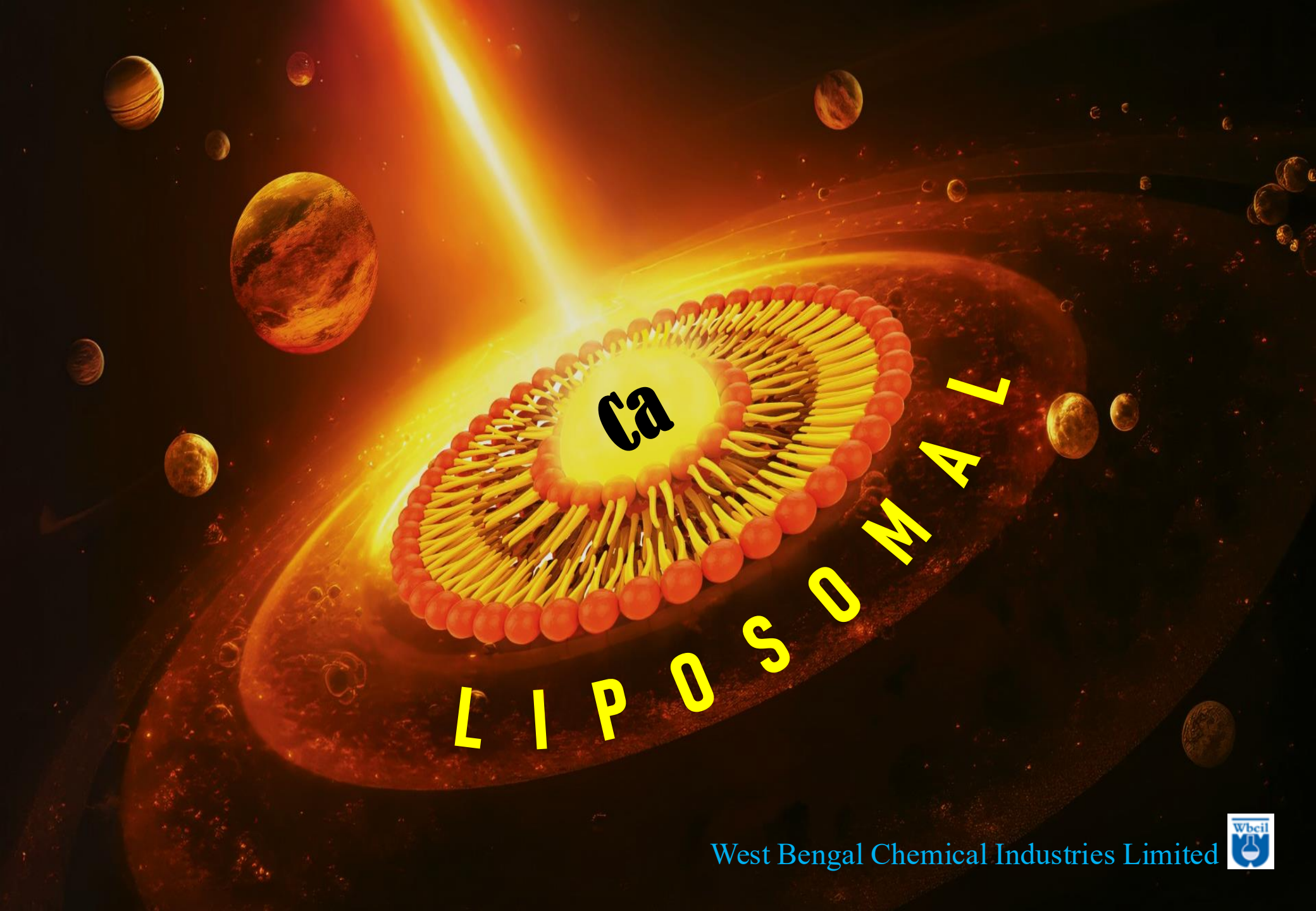

West Bengal Chemical Industries Limited

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A USA FDA-Aligned Framework for Quality & Stability Determination

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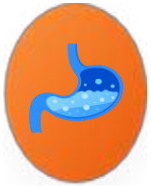
Challenges with Standard Calcium

Poor Absorption

Standard calcium exhibits a modest absorption rate of only ~10%



Enzymatic Breakdown

Free calcium causes metallic taste, nausea, and severe gastric irritation

Intestinal Instability

Free calcium ions are highly unstable within the alkaline environment of the small intestine

WBCIL Liposome: The Guarantee of Purity

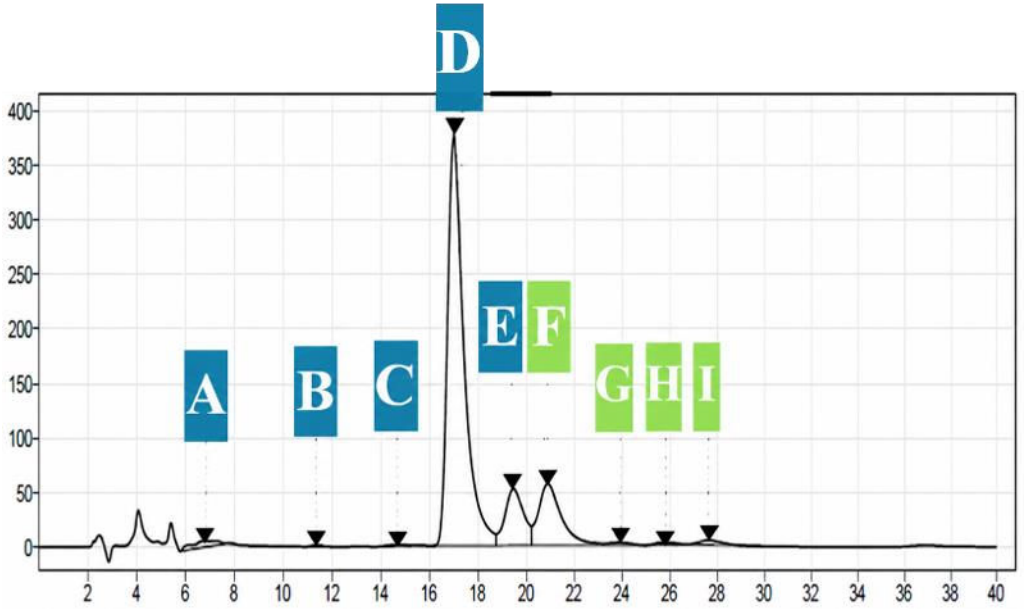


Figure 1 –The chromatogram of a phospholipid constituting a liposome

Phosphatidylcholine (PC-Peak A-E) : 90.07%

Phosphatidylethanolamine (PE-Peak F-I) : 4.39%

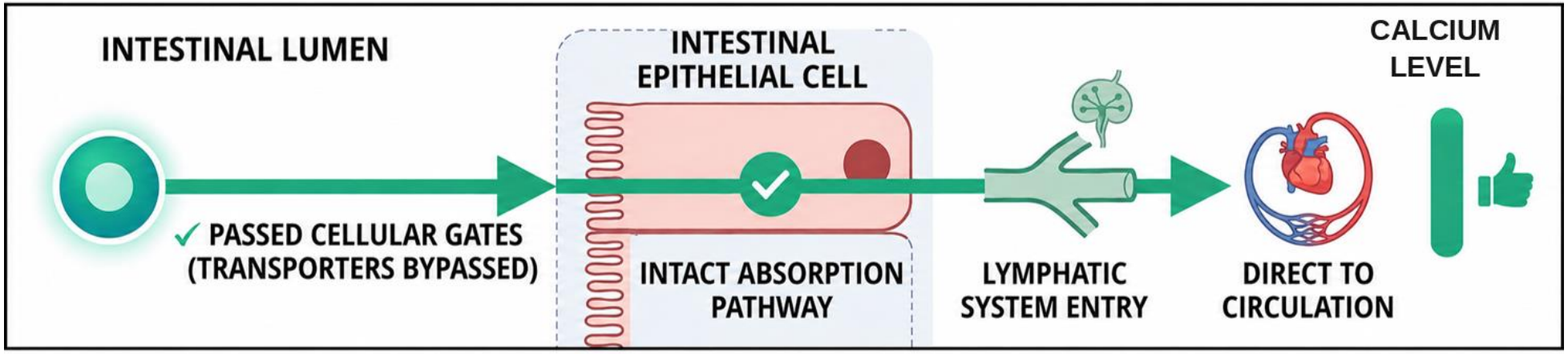
Stronger Shells & Cleaner Product

>90% purity ensures liposomal stability and patient safety by minimizing unwanted lipids

WBCIL Achieved

>94% phospholipid purity with > 90% PC content

Bypassing Natural Barriers



Bypassing Transporters

Instead of struggling through standard cellular gates, intact liposomes enter directly into the lymphatic system

Direct Entry to Systemic Circulation

By migrating directly into the lymphatic system, liposomal calcium avoids liver first-pass metabolism, elevating serum calcium safely and efficiently.

CLINICAL ADVANTAGE: This mimics the efficacy of an IV infusion through a simple, safe oral dose.

Encapsulation Efficiency

Encapsulation Efficiency: The percentage of the active ingredient successfully encapsulated within the protective liposome core.

>70%	82% Achieved
ACCEPTANCE CRITERIA	WBCIL PROPRIETARY PROCESS

KEY ADVANTAGES

- Improves Bioavailability
- Prevents Gastric Irritation
- Boosts Patient Compliance

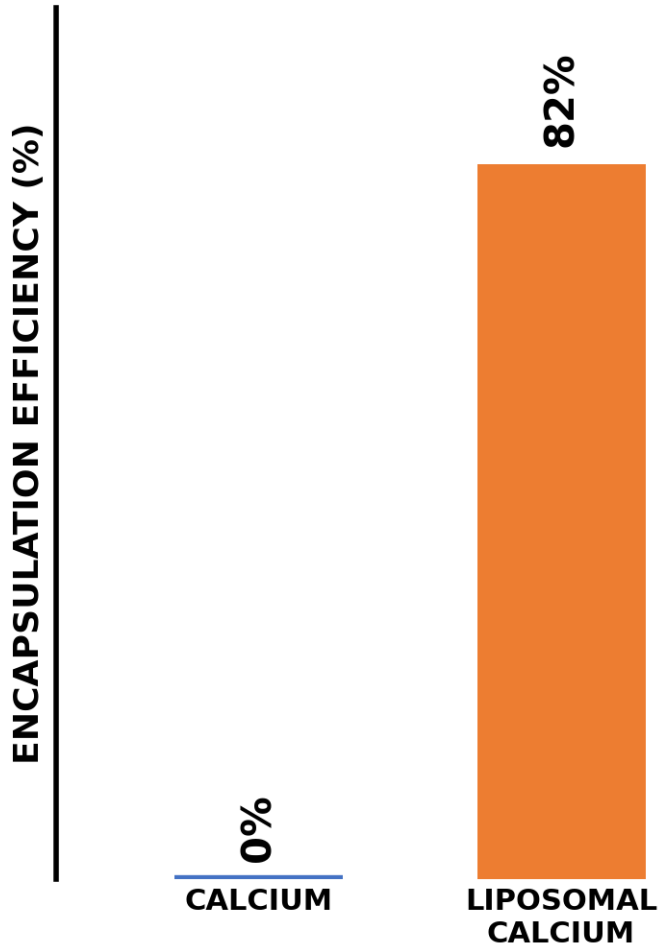
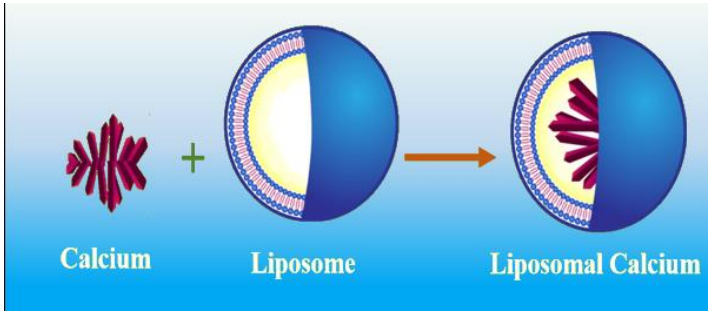


Figure 2: Encapsulation efficiency of Liposomal Calcium

Loading Capacity

Loading Capacity (%): The measure of how much active ingredient is packed into each individual liposome.

>70%	76% Achieved
ACCEPTANCE CRITERIA	0.76 mg of Ca LOADED PER mg of Lipo-Ca



KEY ADVANTAGES

- Helps in Dose Designing
- More Effective Outcomes
- Enables Smaller Capsules

WBCIL Manufacturing Efficacy: *This exceptionally high loading capacity ensures smaller capsule sizes and more effective therapeutic outcomes while maintaining excellent stability.*

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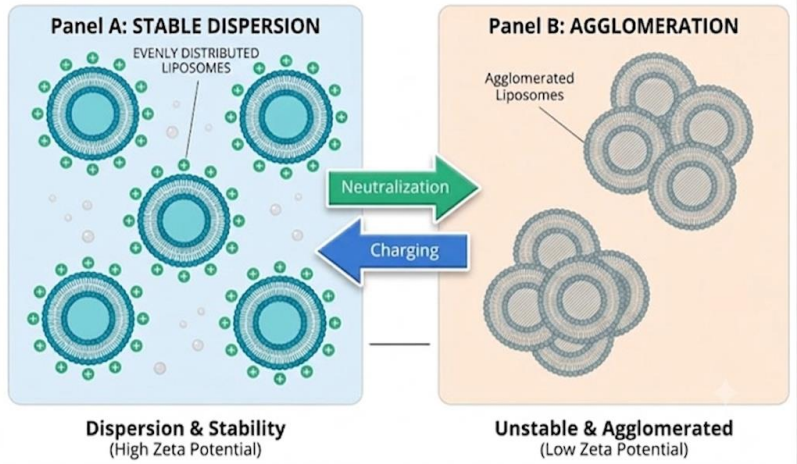
Dynamic Light Scattering Analysis of Liposomal Calcium

A. Zeta Potential: an indicator of the liposome's surface charge

< -25 mV	-37 mV
ACCEPTANCE CRITERIA	WBCIL ACHIEVED ZP



KEY ADVANTAGES

- High Zeta Potential creates a strong repulsion between particles, preventing clumping and ensuring stability.

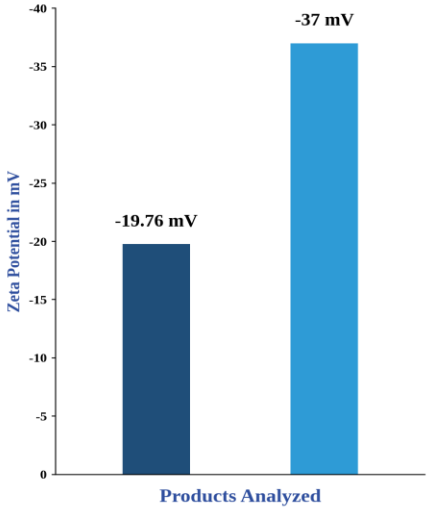


Figure 3: Determination of Zeta Potential

B. Particle Size determination

≤300 nm	249 nm
ACCEPTANCE CRITERIA	WBCIL ACHEIVED

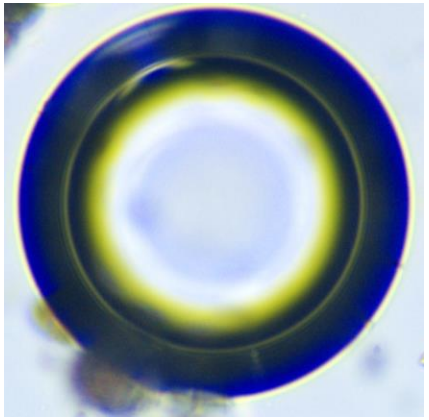


Figure 4A: Microscopic image of a liposomal Calcium

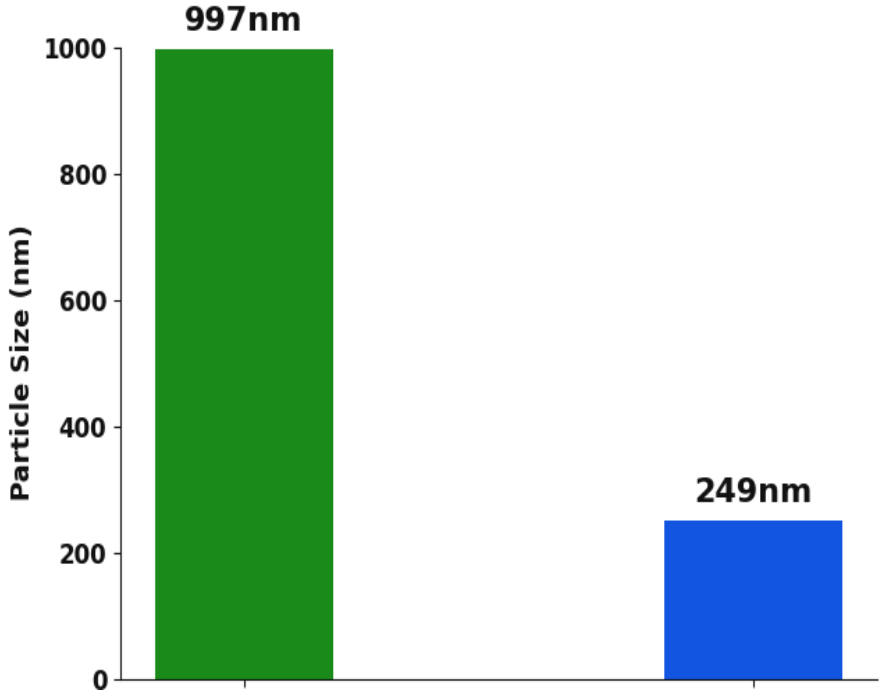


Figure 4B: Particle size of Calcium API vs Liposomal Calcium in solution

KEY ADVANTAGES

- Increased Cellular Uptake

C. Polydispersity Index (PDI): Uniformity in size distribution of liposomes

< 0.50	0.22
ACCEPTANCE CRITERIA	WBCIL ACHIEVED PDI

KEY ADVANTAGES

- Yields superior colloidal stability in the formulation
- Directly contributes to an improved and stable shelf life

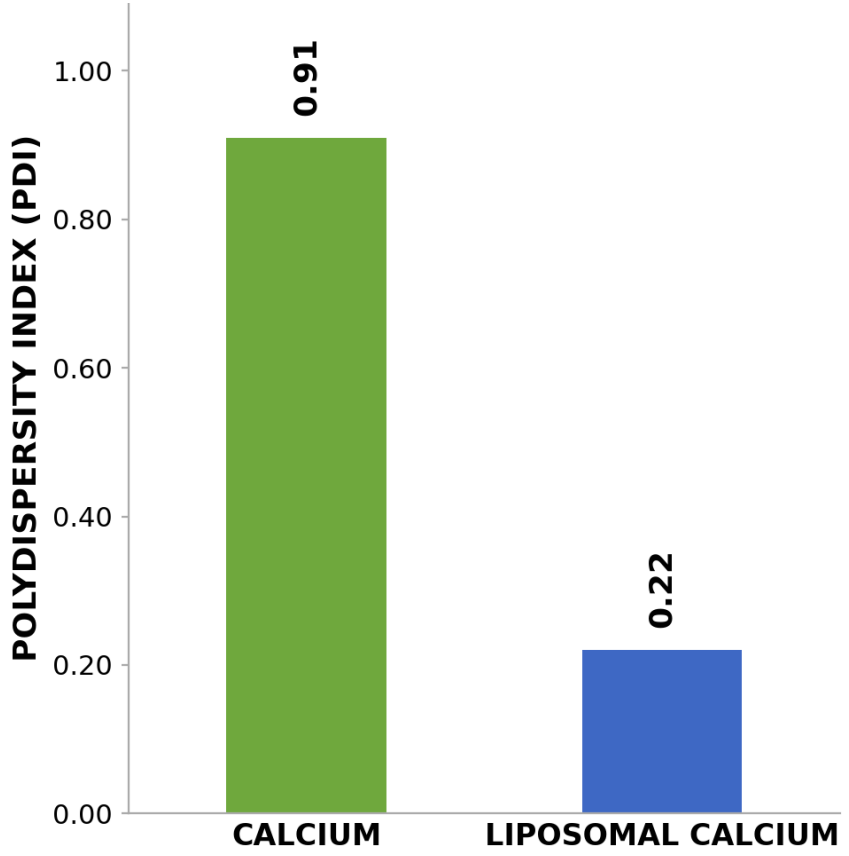
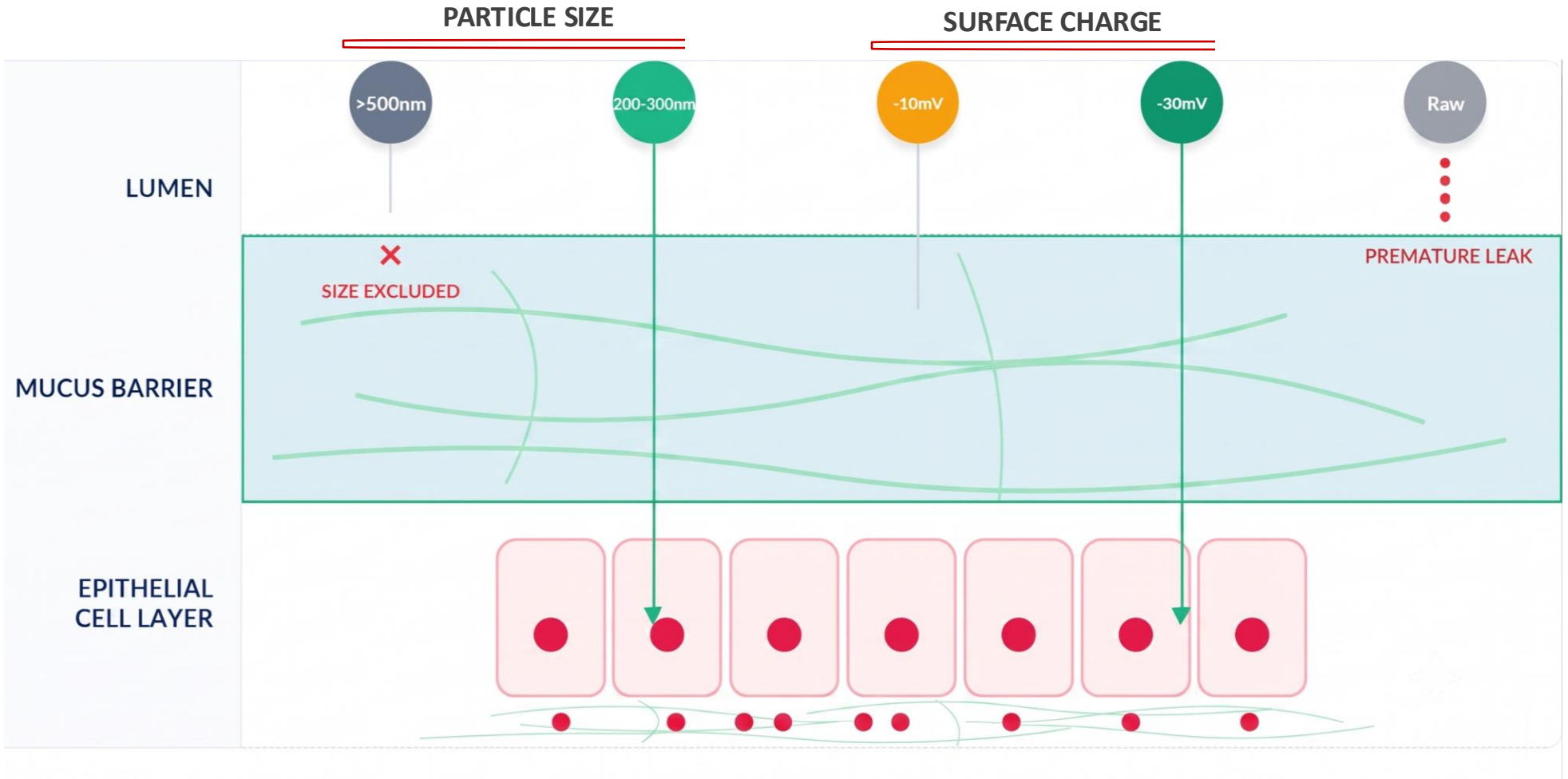


Figure 5: Polydispersity Index (PDI) of Calcium API vs Liposomal Calcium in solution

Absorption of Liposomal Calcium Represented Schematically on a Cellular Cross-Section



The Fingerprint Test: Fourier Transform Infrared Spectroscopy (FTIR) of Liposomal Calcium

FTIR acts like a "molecular fingerprint". Every ingredient has a unique signal.

Feature Observed	Raw Calcium API	WBCIL Liposomal Calcium
Lipid Bilayer Signal (2924 & 2855 cm^{-1})	Absent	Present & Verified
Carbonate Stretch (1394-1438 cm^{-1})	Strong & Broad	Shifted & Broadened
Structure Proof	Sharp (Crystalline)	Broad & Hybrid (Encapsulated)

The Lipid Ester Peak (C=O) at 1736-1738 cm^{-1} shifts significantly in the Liposomal Calcium, indicating a direct molecular interaction between Calcium and the phospholipid

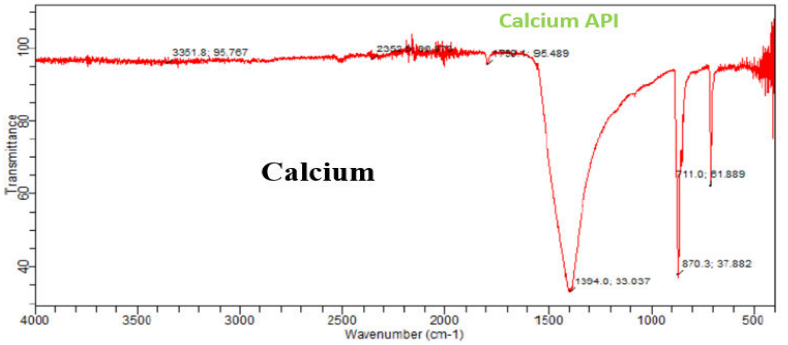


Figure 6A: IR Transmission spectrum of Calcium API

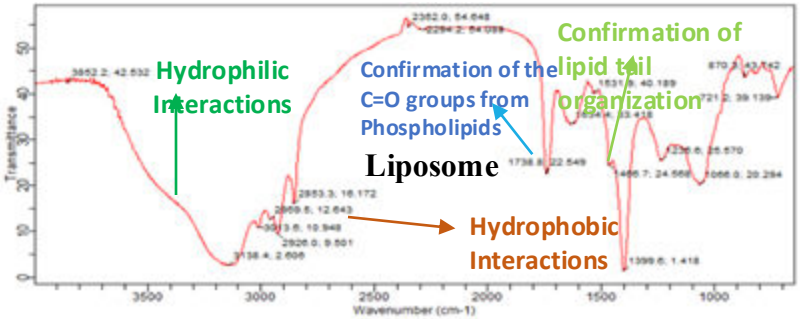


Figure 6B: IR Transmission spectrum of Empty Liposome

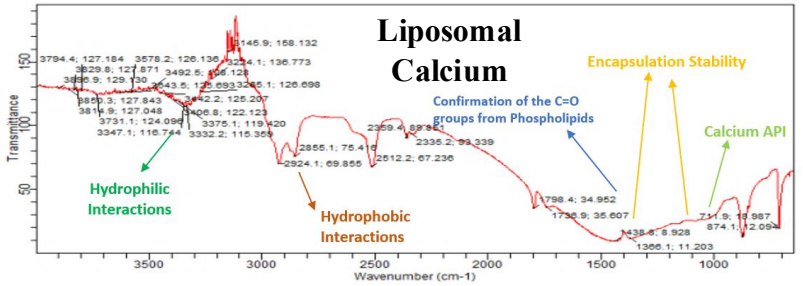


Figure 6C: IR Transmission spectrum of Liposomal Calcium

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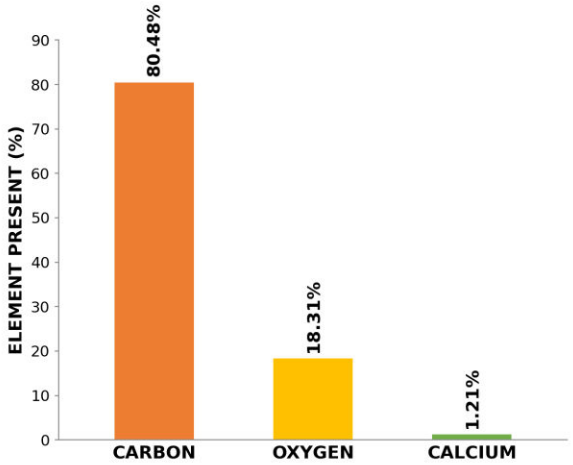
The Surface Proof: Energy-Dispersive X-ray Spectroscopy

A surface scan using EDAX examines the particle's surface. If calcium is detectable on the surface, it's not fully encapsulated.

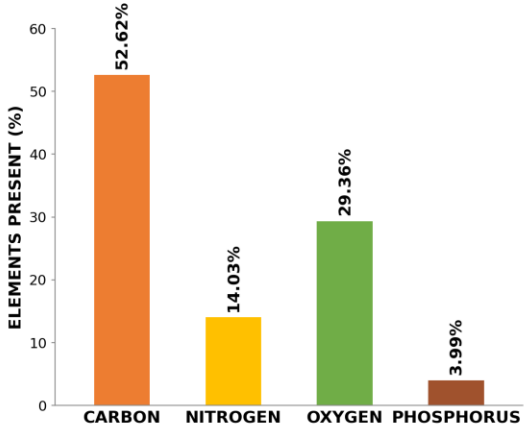
Element Detected	Standard Calcium API	WBCIL Liposomal Calcium
Calcium	Present	Absent
Nitrogen & Phosphorous (Present in lipid)	Absent	Present (Lipid Bilayer)

CONCLUSION: Successful Encapsulation of Active Calcium

7A: EDAX of Calcium Carbonate



7B: EDAX of Liposomal Calcium



Scanning Electron Microscope (SEM) Image of Liposomal Calcium

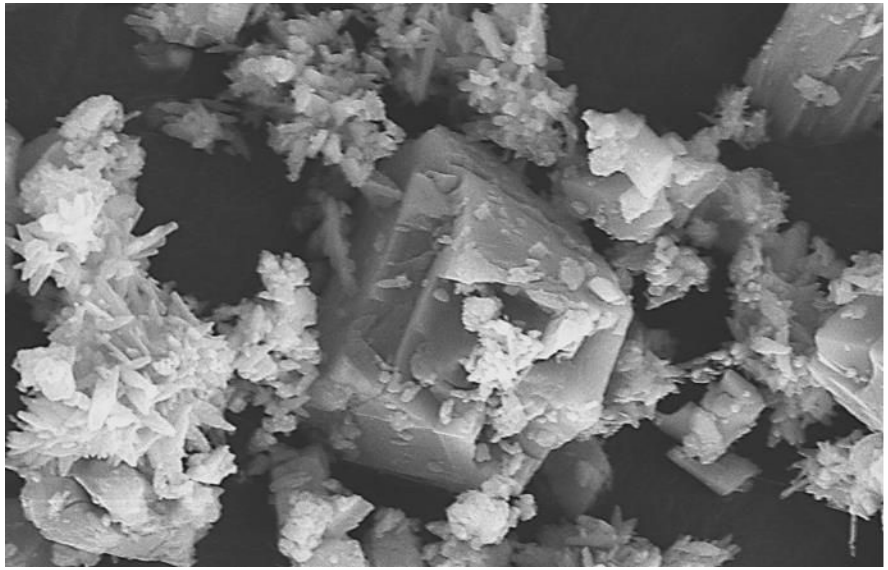


Figure 8A: SEM image of Calcium API

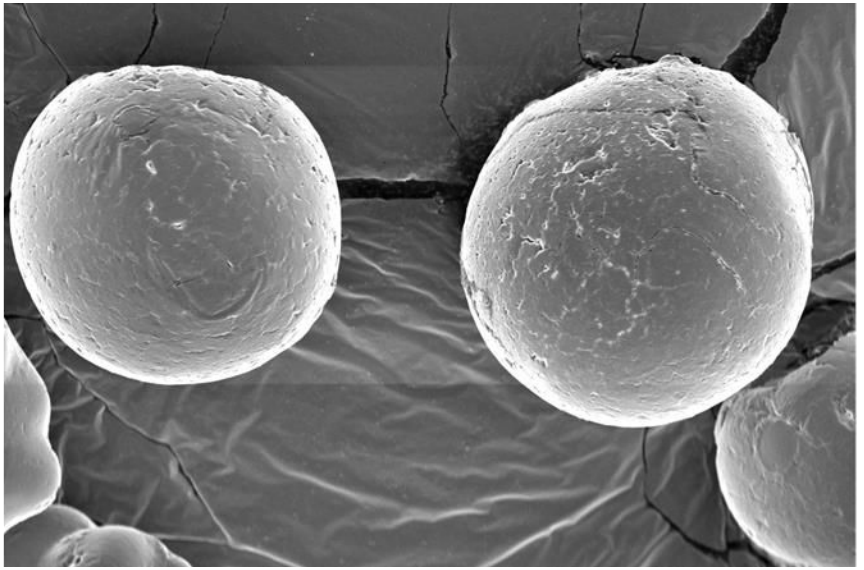


Figure 8B: SEM image of Liposomal Calcium

WBCIL Liposomes are perfectly smooth spheres. This morphology:

- Enhances overall stability
- Ideal for efficient drug delivery

The Accelerated Stability Test

We tested our **liposomal Calcium** under Extreme Conditions (40°C ± 2°C and 75% ± 5% Humidity) for 6 months to see if it would leak or lose power, resulting in a decrease in iron content

98.8%
ACTIVE RETENTION

1.12%
TOTAL ASSAY LOSS

OUTCOME: Efficient structural preservation ensures longer shelf-life

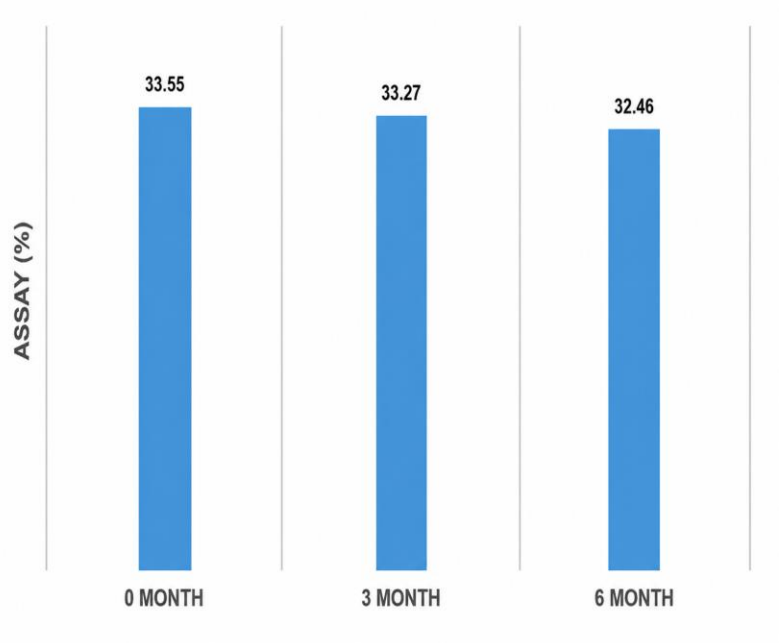


Figure 9: Determination of the Assay% of Liposomal calcium observed under accelerated condition (40°C ± 2°C and 75% ± 5% Humidity) for 6 months

The Real-Time Stability Test

Under normal shelf conditions (30°C ± 2°C and 65% ± 5% Humidity) for 36 months, the **liposomal calcium** remains even more resilient, ensuring the patient gets the full dose every time.

97.20%
ACTIVE RETENTION

2.80%
TOTAL ASSAY LOSS

OUTCOME: Complete structural preservation prevents premature release, assuring standard dose delivery every time.

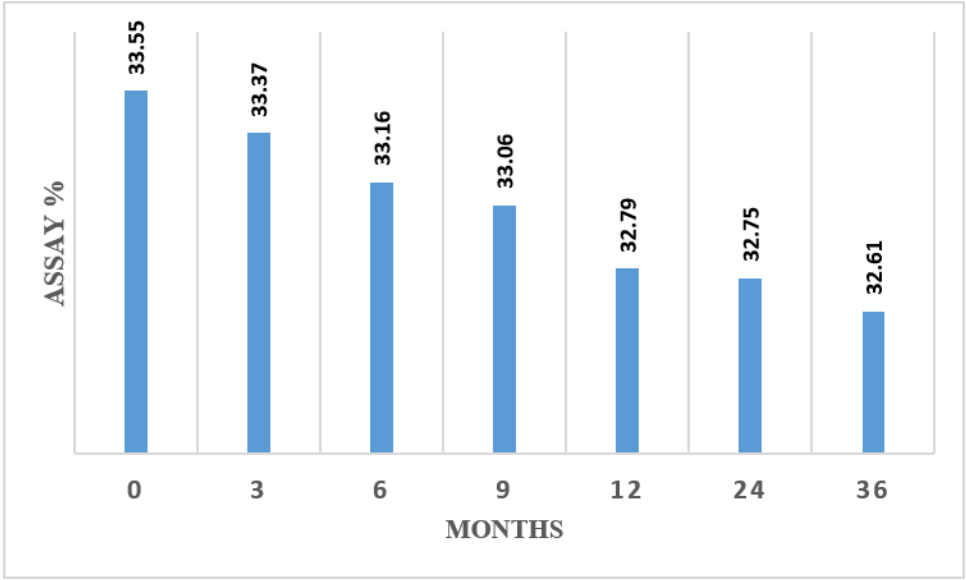


Figure 10: Determination of the Assay% of Liposomal calcium observed under real-time condition (30°C ± 2°C and 65% ± 5% Humidity) for 36 months

Differential Scanning Calorimetry (DSC): Molecular Proof of Quality

DSC: A thermal test that provides molecular proof that the active ingredient is successfully encapsulated inside the liposome rather than just being physically mixed

Transition Temperature Peak (T_m)

Calcium	~410°C
Empty Liposome	187 - 291°C
Liposomal calcium	293 - 453°C

Thermal analysis by DSC provides definitive proof that the calcium is encapsulated, creating a superior and more stable nutrient delivery system.

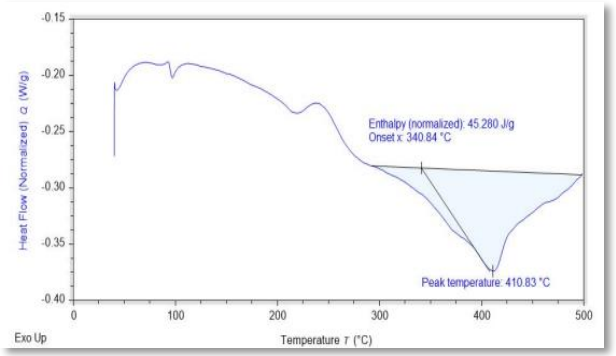


Figure 11A: DSC Thermogram of of Calcium API

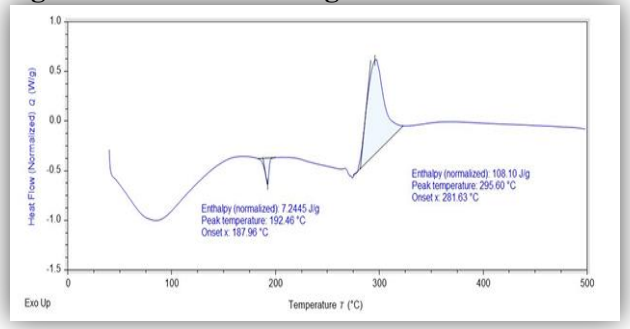


Figure 11B: DSC Thermogram of Empty Liposome

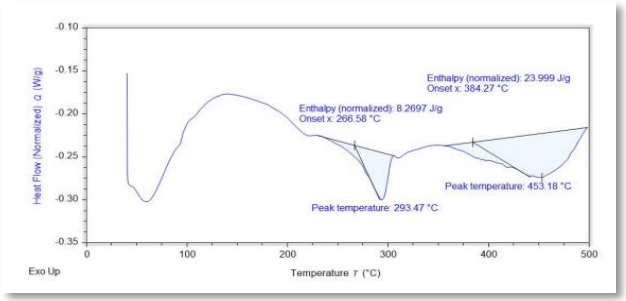


Figure 11C: DSC Thermogram of Liposomal Calcium

Summary

1. Encapsulation Efficiency & Capacity

a. Encapsulation Efficiency:	**82%**	Minimal loss & taste masking
b. Loading Capacity:	**76%**	Efficient dosing, lower cost

2. Particle Characteristics & Stability

a. Zeta Potential:	**-37 mV**	Liposomal stability
b. Particle Size:	**249 nm**	Improved cellular uptake
c. PDI:	**0.22**	Uniform, stable liposomes

3. Structural & Chemical Confirmation

a. FTIR:	**Spectral shift**	Calcium integrated, not physically mixed
b. EDAX:	**No surface Calcium**	Calcium encapsulated within a liposome
c. SEM:	**Smoother, spherical particle**	Successful encapsulation

4. Thermal Stability & Integrity

a. Leakage & Stability:	**< 3% leakage**	Long-term product stability
b. DSC :	**Elevated Tm**	Ensures thermal stability

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THANK YOU

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