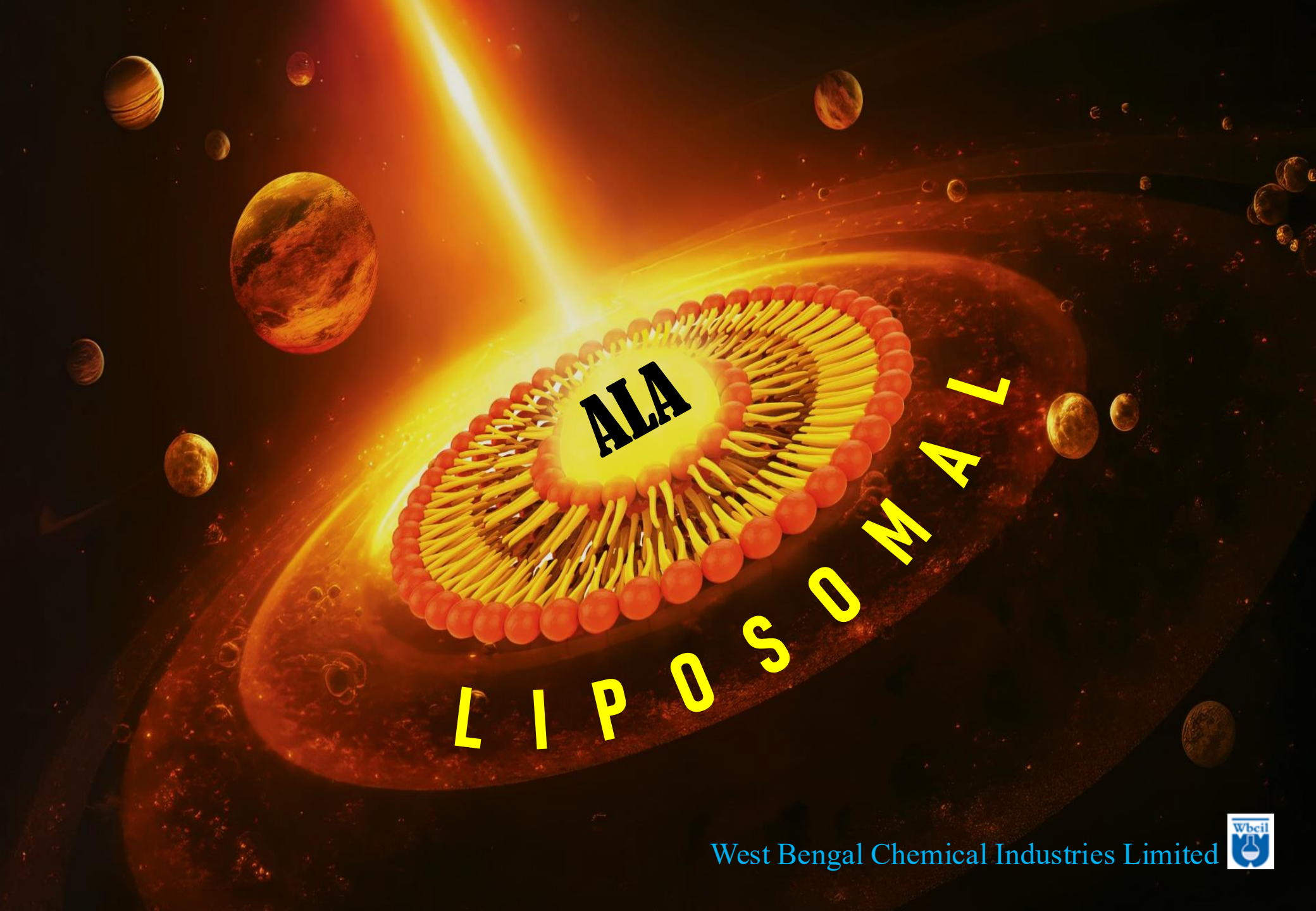

West Bengal Chemical Industries Limited

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A USA FDA-Aligned Framework for Quality & Stability Determination

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Challenges with Standard Alpha Lipoic Acid (ALA)

Limited Bioavailability

Only 20-30% oral absorption reaches systemic circulation due to GI degradation

GI Intolerance

Highly susceptible to oxidation in GI tract and during storage, compromising efficacy

Poor cellular uptake

Limited transport across cell membranes restricts intracellular antioxidant action despite availability

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WBCIL Liposome: The Guarantee of Purity

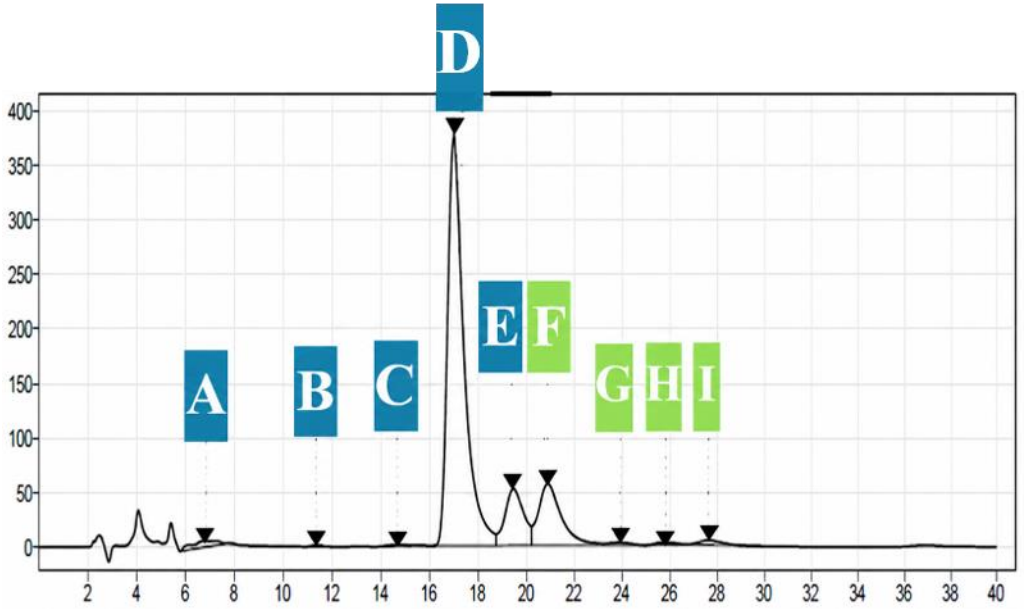

Figure 1 –The chromatogram of a phospholipid constituting a liposome

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 minimising unwanted lipids

WBCIL Achieved

> 94% phospholipid purity with > 90% PC content

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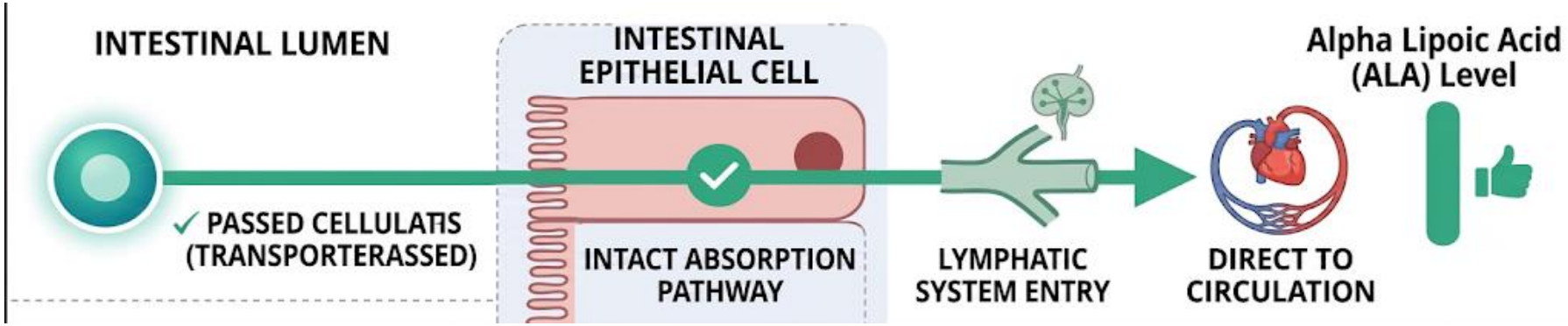
Bypassing Natural Barriers



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 ALA avoids liver first-pass metabolism, elevating serum ALA 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%	80% Achieved
ACCEPTANCE CRITERIA	WBCIL PROPRIETARY PROCESS

KEY ADVANTAGES

- Improves Bioavailability
- Protects ALA from oxidation
- Prevents Gastric Irritation
- Boosts Patient Compliance

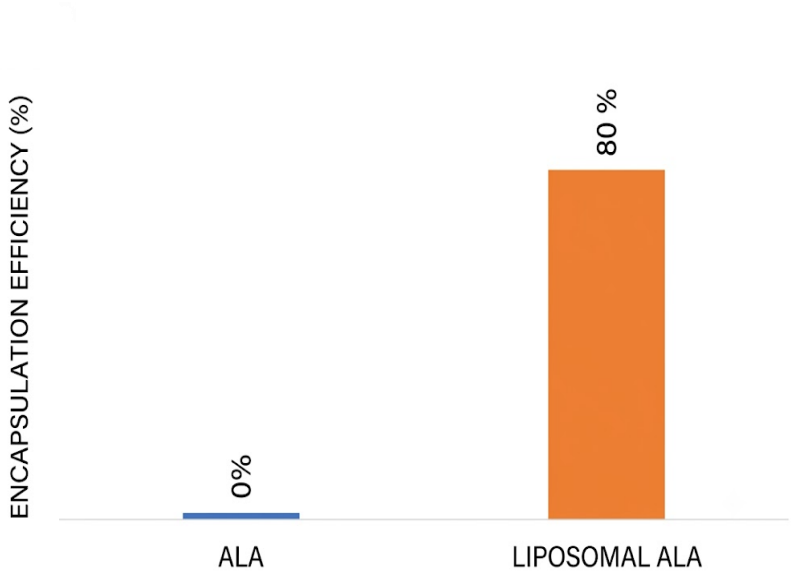
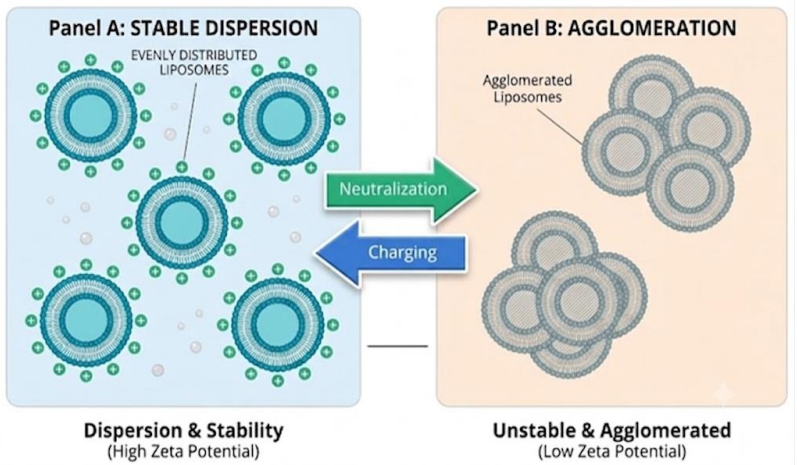


Figure 2: Encapsulation efficiency of Liposomal ALA

Dynamic Light Scattering Analysis of Liposomal ALA

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

< -25 mV	-35 mV
ACCEPTANCE CRITERIA	WBCIL ACHIEVED ZP



KEY ADVANTAGES

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

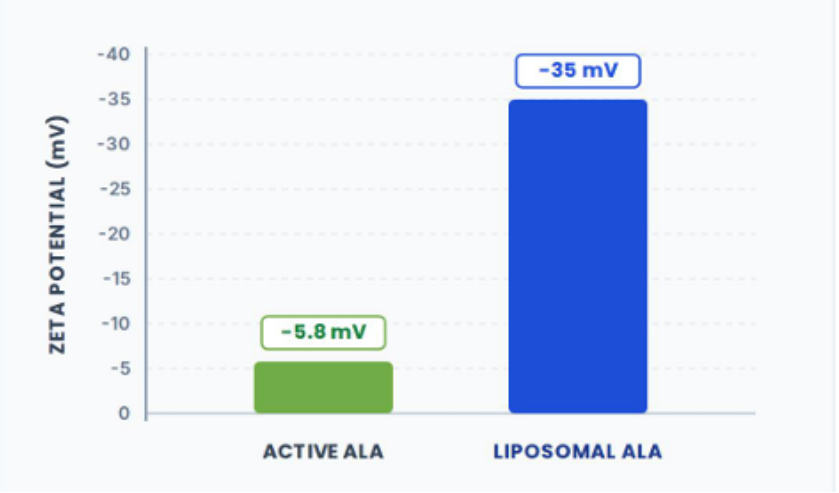


Figure 3: Determination of Zeta Potential

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B. Particle Size determination

≤300 nm
ACCEPTANCE CRITERIA

250 nm
WBCIL ACHEIVED

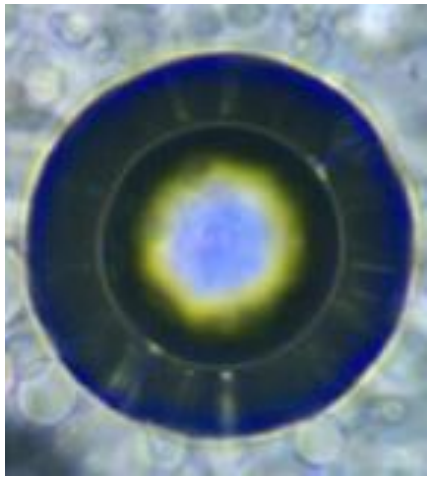


Figure 4A: Microscopic image of a liposomal ALA

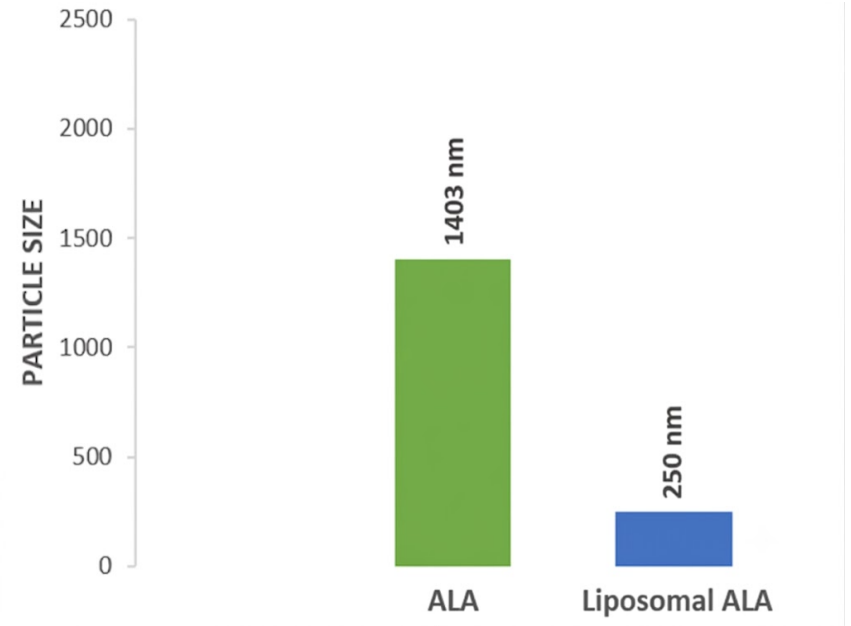


Figure 4B: Particle size of Active ALA vs Liposomal ALA in solution

KEY ADVANTAGES

- Increased Cellular Uptake

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

< 0.50	0.202
ACCEPTANCE CRITERIA	WBCIL ACHIEVED PDI

KEY ADVANTAGES

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

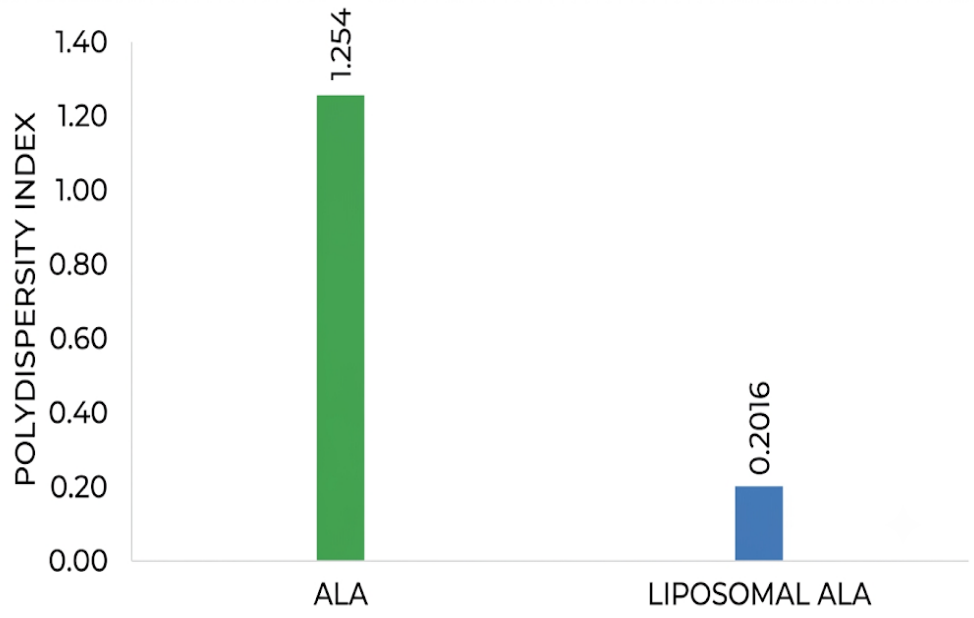
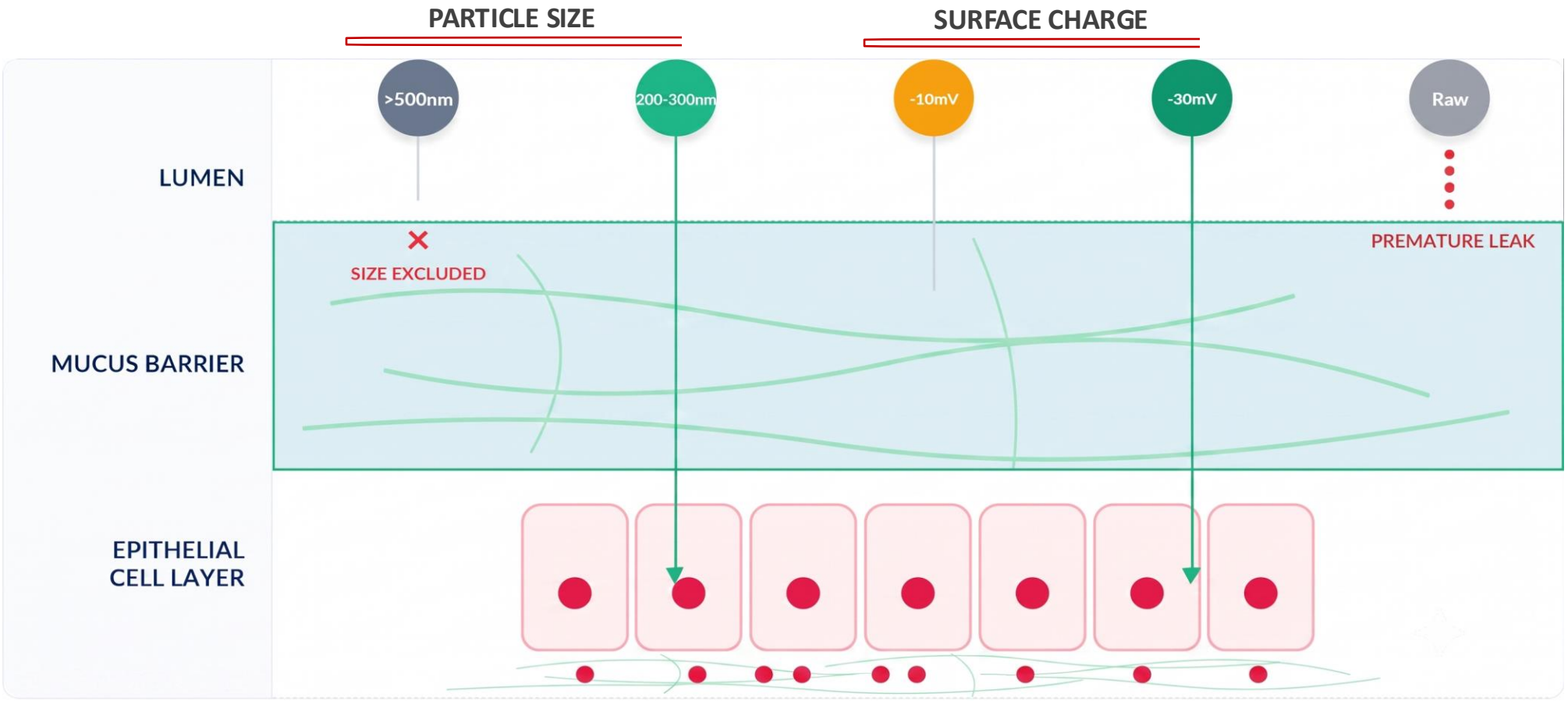


Figure 5: Polydispersity Index (PDI) of ALA as Active Ingredient vs Liposomal ALA in solution

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



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

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

Feature Observed	Raw ALA	Empty Liposome	WBCIL Liposomal ALA
Lipid Bilayer Signal	Absent	Present	Present & Verified
ALA Carbonyl & Sulphur Peaks	Sharp, Strong & Crystalline	Absent	Modified & Broadened
Structure Proof	Physical Powder	Empty liposome	Embedded in Lipid Matrix

The "Fingerprint" Region : Carbonyl (1705 cm^{-1}) & Sulphur (684 cm^{-1}) of liposomal ALA shows a merged pattern, indicating that the ALA is fully encapsulated within the liposome

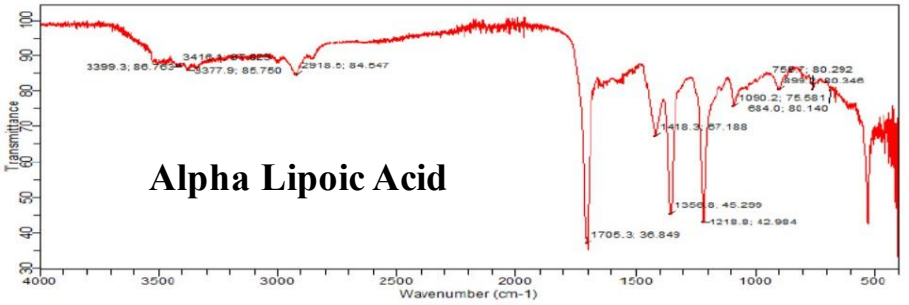


Figure 6A: FTIR Spectra of ALA API

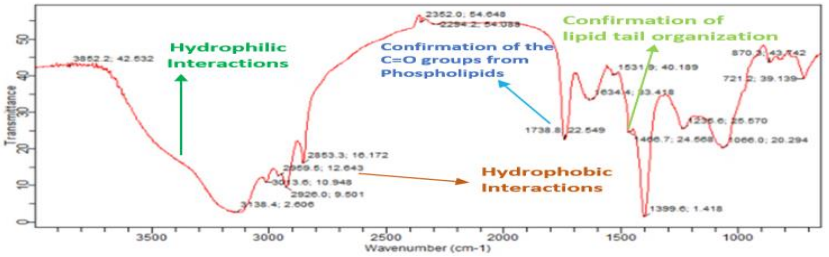


Figure 6B: FTIR Spectra of Empty Liposome

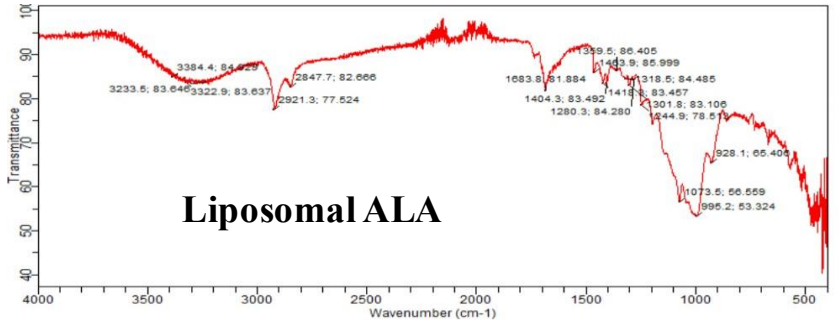


Figure 6C: FTIR Spectra of Liposomal ALA

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The Surface Proof: Energy-Dispersive X-ray Spectroscopy (EDAX)

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

Element Detected	Standard ALA	WBCIL Liposomal ALA
Sulphur	Present	**Absent (Surface)**
Phosphorus & Nitrogen (Present in Lipid)	Absent	**Present (Lipid Bilayer)**

CONCLUSION: Successful Encapsulation of Active ALA ensures zero metallic taste

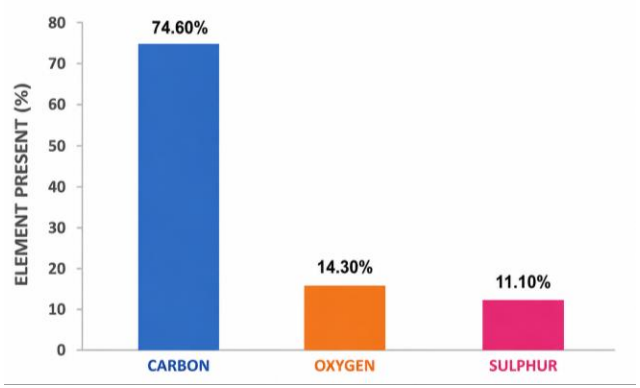


Figure 7A: EDAX of Standard ALA API

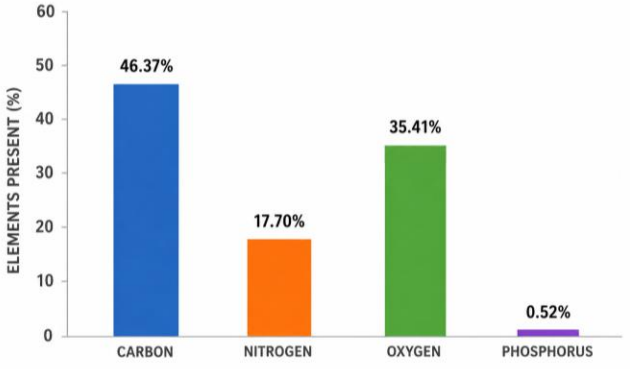


Figure 7B: EDAX of Liposomal ALA

Scanning Electron Microscope (SEM) Image of Liposomal ALA

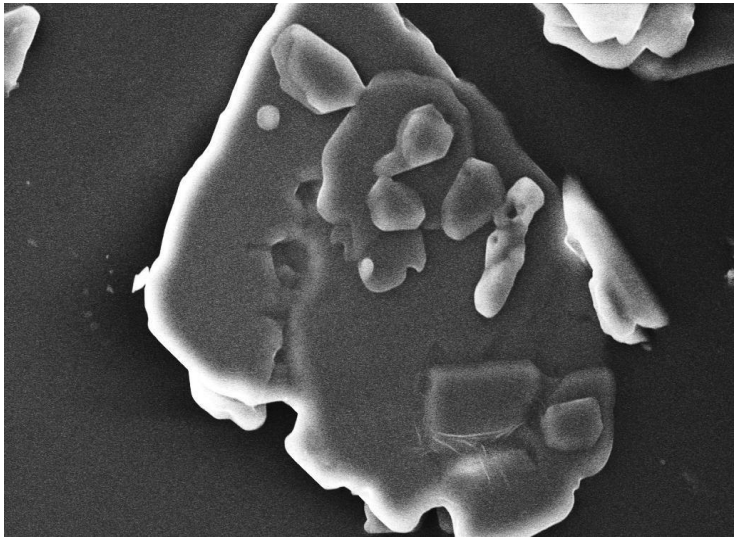


Figure 8A: SEM image of ALA API

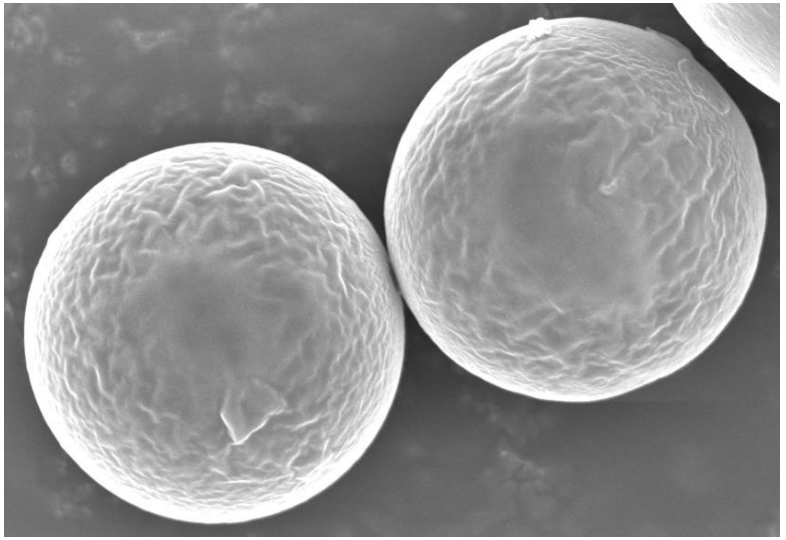


Figure 8B: SEM image of Liposomal ALA

WBCIL Liposomes are perfectly smooth spheres. This morphology:

- Enhances overall stability
- Ideal for efficient drug delivery

The Accelerated Stability Test

We tested our **liposomal ALA** 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 ALA content

97.69%
ACTIVE RETENTION

2.31%
TOTAL ASSAY LOSS

OUTCOME: Complete structural preservation ensures longer shelf-life

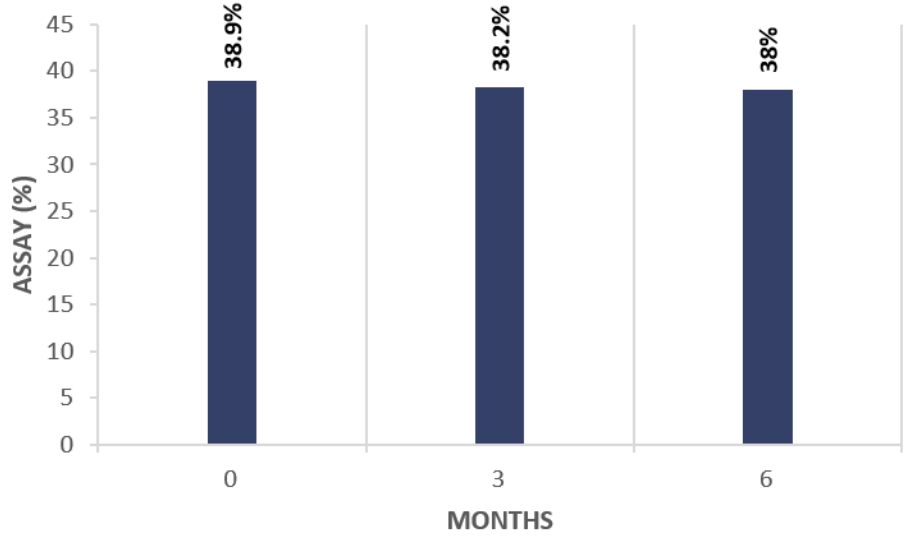


Figure 9: Determination of the Assay% of Liposomal ALA observed under accelerated condition (40°C ± 2°C and 75% ± 5% Humidity) for 6 months

The Real-Time Stability Test

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

97.25%
ACTIVE RETENTION

2.75%
TOTAL ASSAY LOSS

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

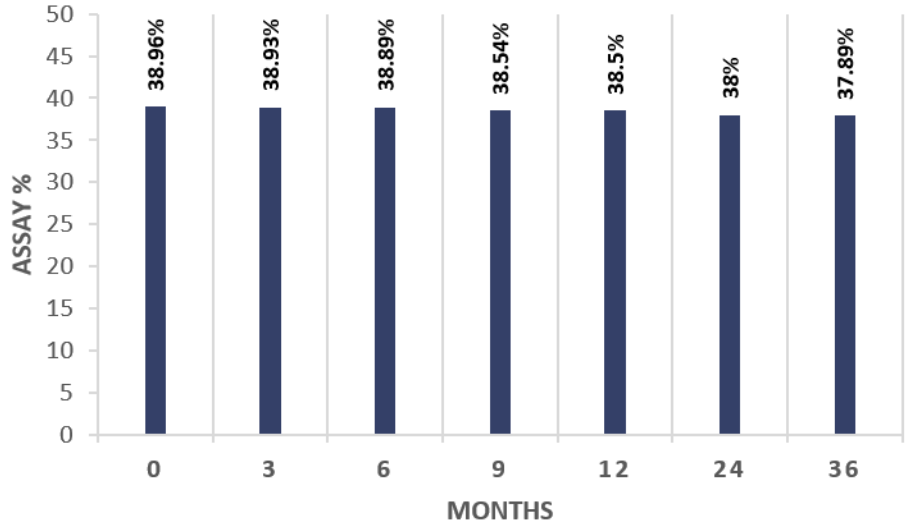
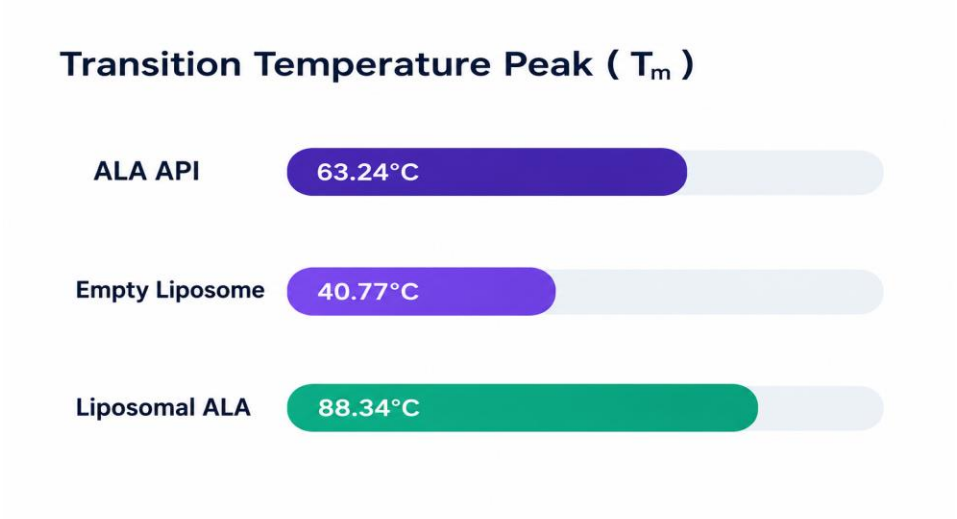


Figure 10: Determination of the Assay% of Liposomal Alpha Lipoic Acid observed under real-time condition (30°C ± 2°C and 65% ± 5% Humidity) for 36 months

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



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

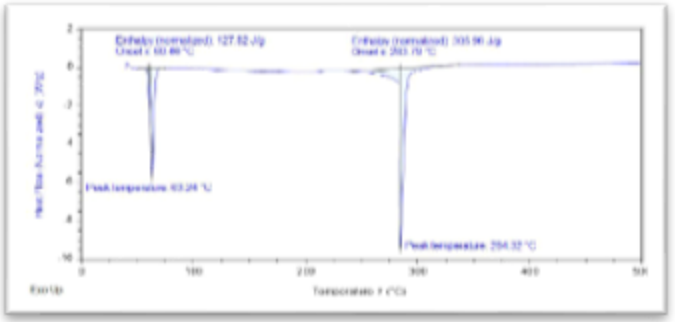


Figure 11A: DSC Thermogram of ALA API

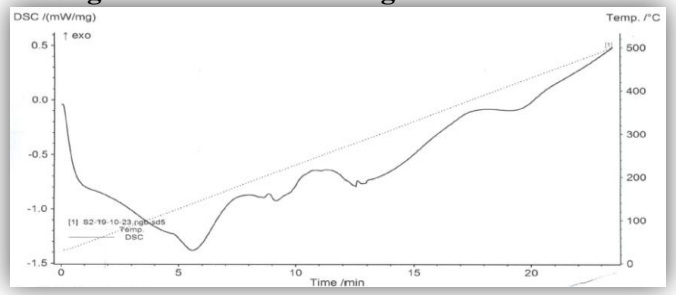


Figure 11B: DSC Thermogram of Empty Liposome

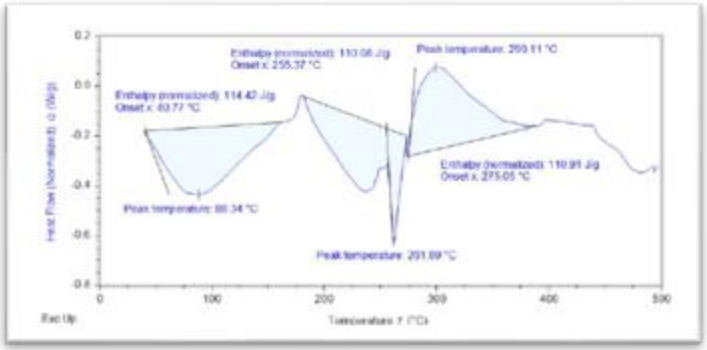


Figure 11C: DSC Thermogram of Liposomal ALA

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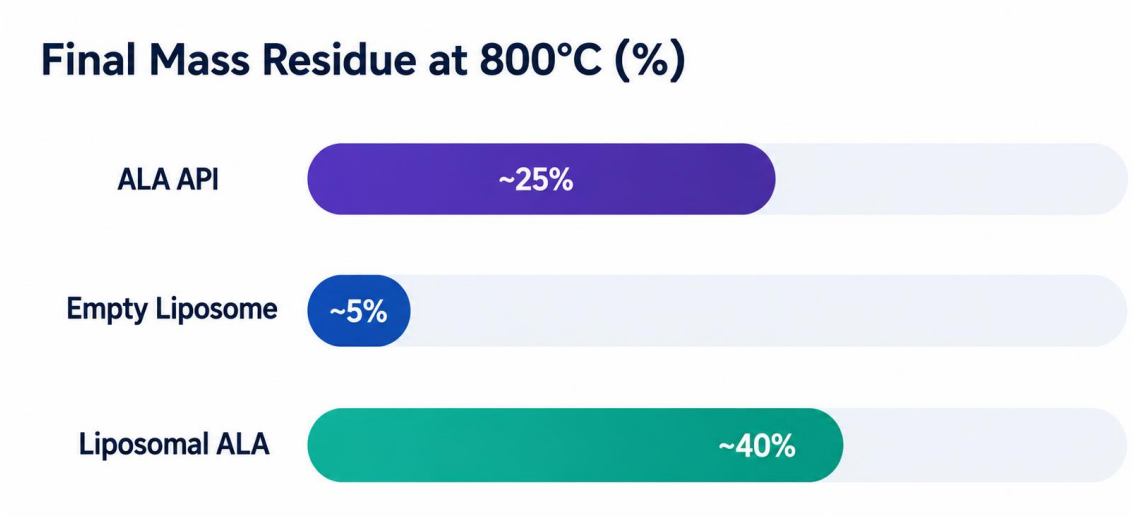
Thermogravimetric Analysis (TGA): The Heat Resistance Test

Thermogravimetric Analysis (TGA) measures mass change as a function of temperature to determine thermal stability and composition.



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

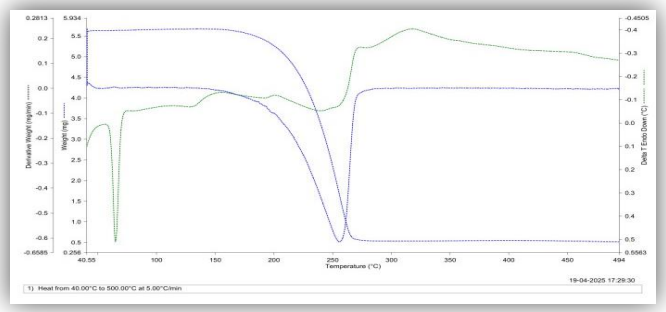


Figure 12A: TGA Thermogram of ALA API

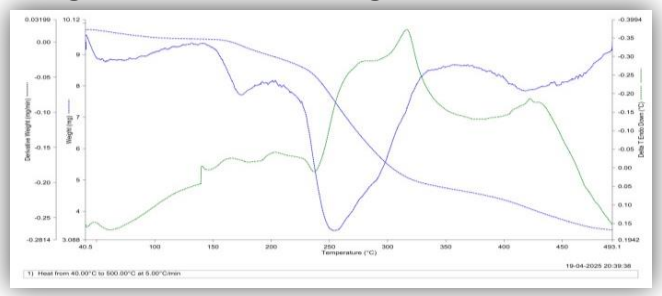


Figure 12B: TGA Thermogram of Empty Liposome

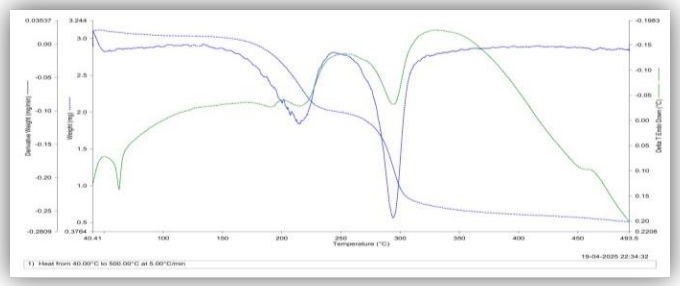


Figure 12C: TGA Thermogram of Liposomal ALA

Summary

1. Encapsulation Efficiency & Capacity

a. Encapsulation Efficiency:	**80%**	Minimal loss & taste masking

2. Particle Characteristics & Stability

a. Zeta Potential:	**-35 mV**	Liposomal stability
b. Particle Size:	**250 nm**	Improved cellular uptake
c. PDI:	**0.20**	Uniform, stable liposomes

3. Structural & Chemical Confirmation

a. FTIR:	**Spectral shift**	ALA integrated, not physically mixed
b. EDAX:	**No surface Sulphur**	ALA 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 & TGA:	**Elevated Tm**	Ensures thermal stability

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THANK YOU

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