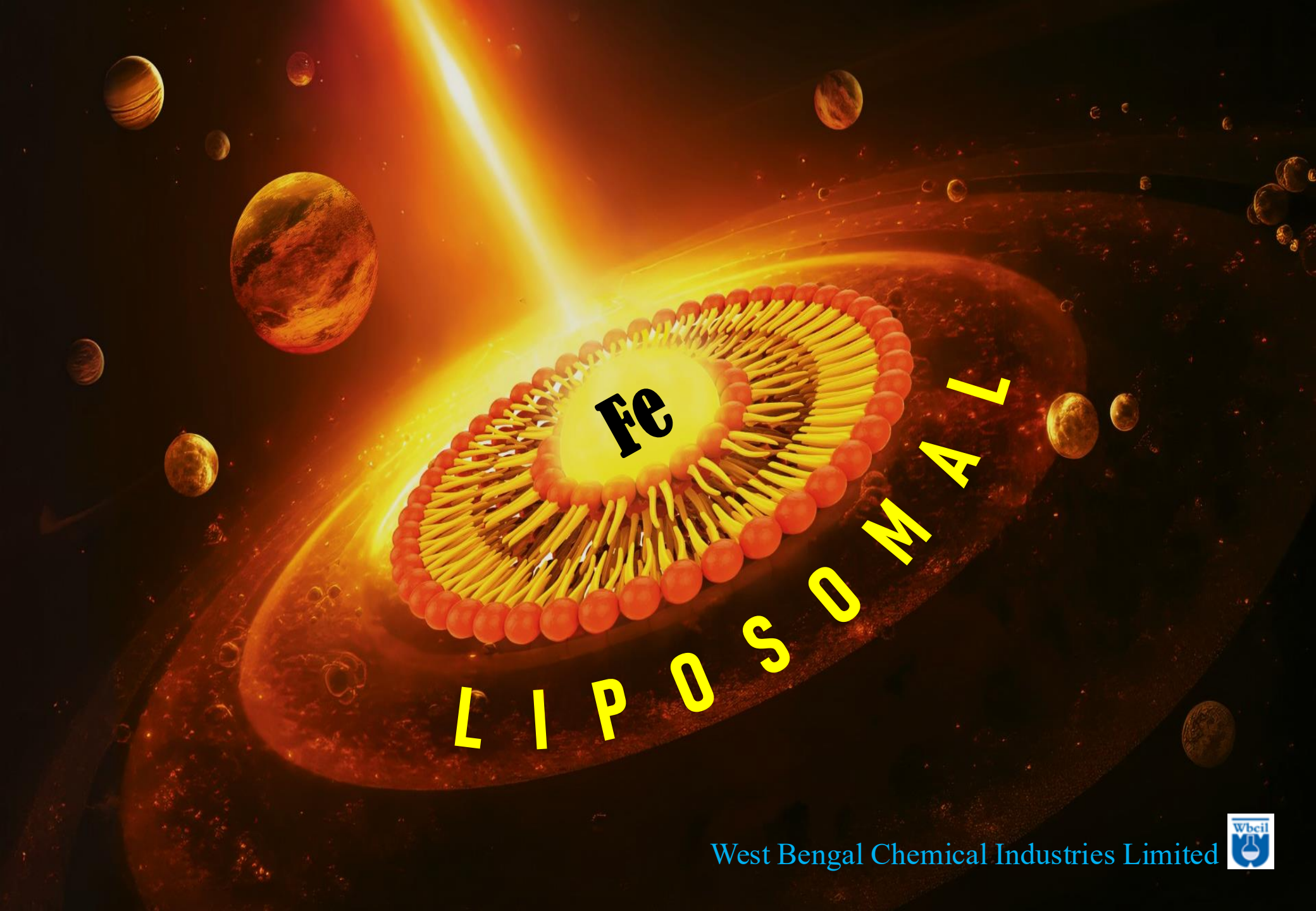




LIPOSOMAL

Fe

West Bengal Chemical Industries Limited



A USA FDA-Aligned Framework for Quality & Stability Determination

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Challenges with Standard Iron



Poor Absorption

Standard salts suffer from low solubility, with only 5% to 15% reaching the blood stream.



GI Intolerance

Free iron causes an unpleasant metallic taste, nausea, and severe mucosal irritation.



Inflammatory Roadblocks

Inflammation triggers hepcidin activation, blocking standard absorption pathways.

WBCIL Liposome: The Guarantee of Purity

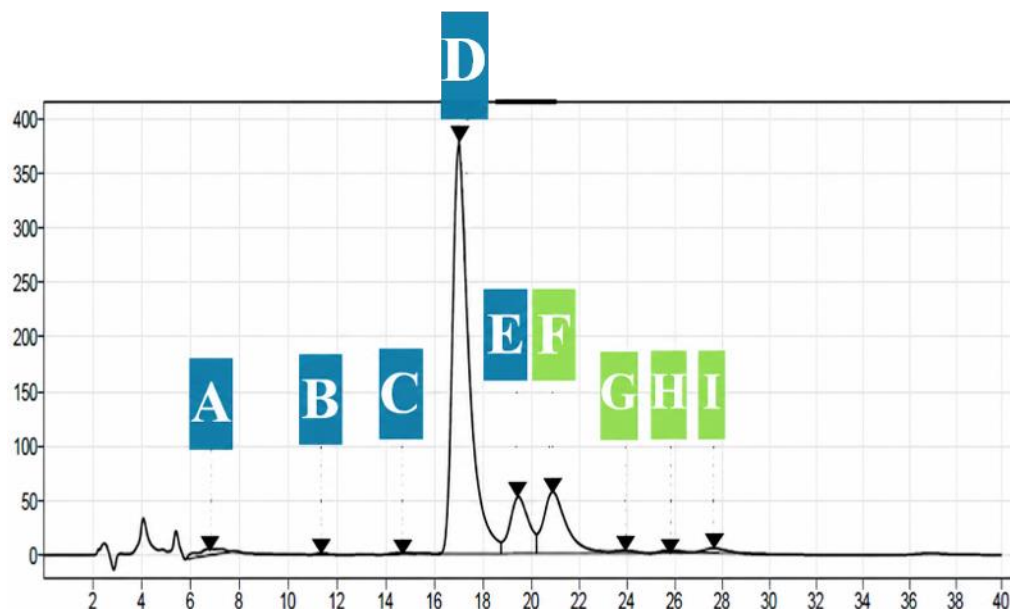


Figure 1 –The chromatogram of a phospholipid constituting a liposome

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

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



Stronger Shells & Cleaner Product

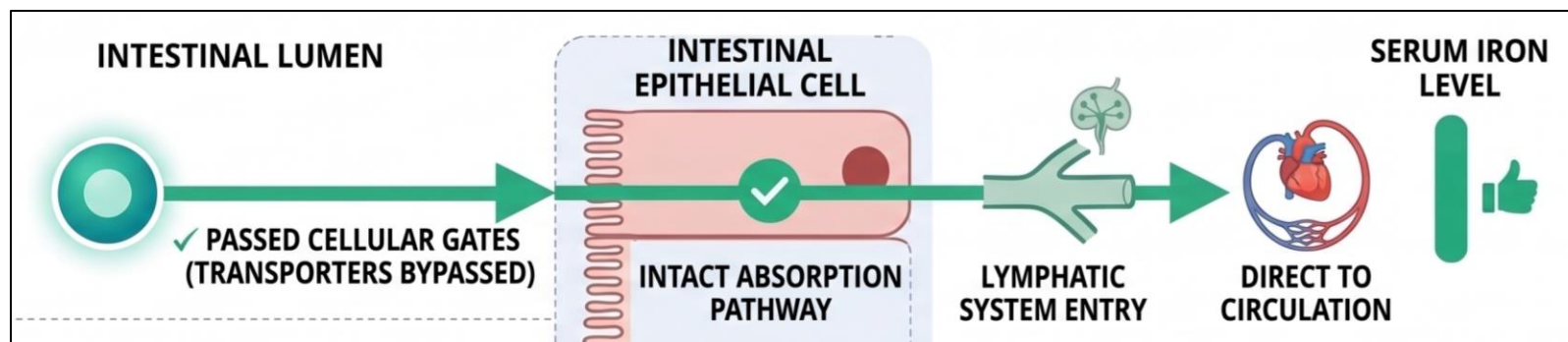
>90% purity ensures liposomal stability
and patient safety by minimising
unwanted lipids



WBCIL Achieved

>94% phospholipid purity with > 90%
PC content

Bypassing Natural Barriers



Bypassing Transporters

Intact liposomes enter directly into the lymphatic system



Direct Entry to Systemic Circulation

Liposomal iron avoids liver first-pass metabolism, elevating serum iron 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%

ACCEPTANCE CRITERIA

80% Achieved

WBCIL PROPRIETARY PROCESS

KEY ADVANTAGES

- ✓ Improves Bioavailability
- ✓ Prevents Gastric Irritation
- ✓ Masks Metallic Iron Taste
- ✓ Boosts Patient Compliance

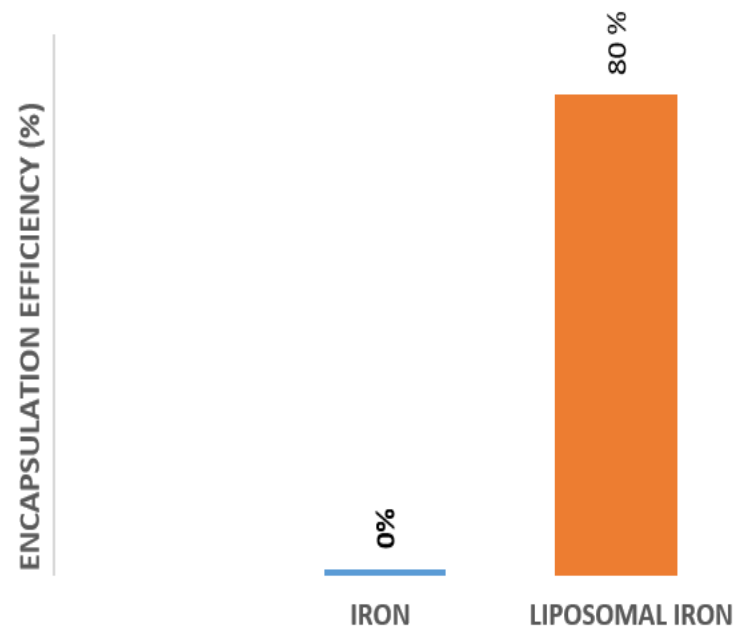


Figure 2: Encapsulation efficiency of Liposomal Iron

Loading Capacity

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

> 70%

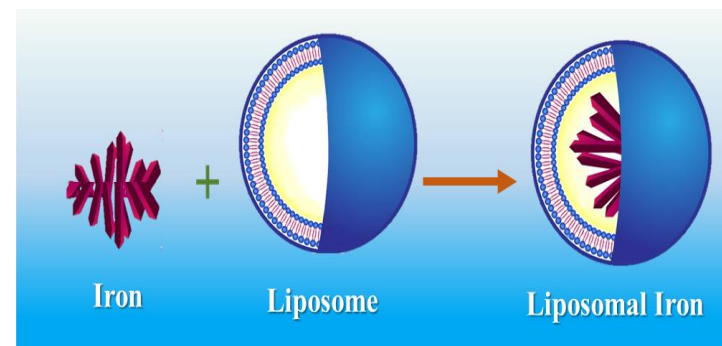
ACCEPTANCE CRITERIA

71% Achieved

0.71 mg of Fe LOADED PER mg of Lipo-Fe

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.

Dynamic Light Scattering Analysis of Liposomal Iron

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

< -25 mV
ACCEPTANCE CRITERIA

-30 mV
WBCIL ACHIEVED ZP

KEY ADVANTAGES

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

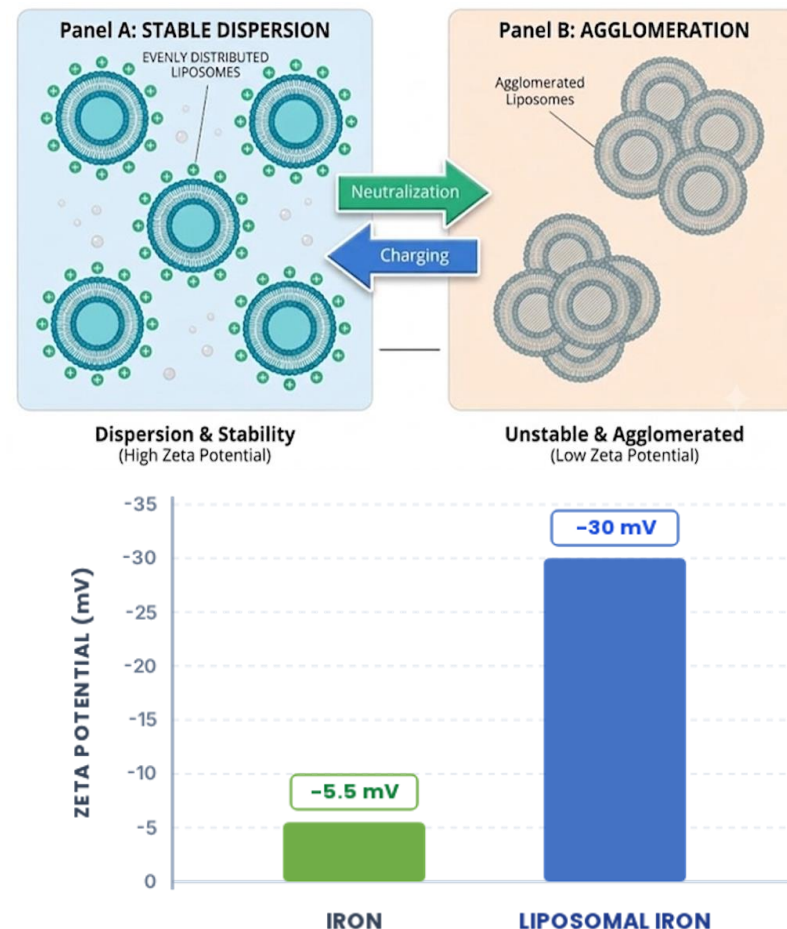


Figure 3: Determination of Zeta Potential

B. Particle Size determination

≤ 300 nm
ACCEPTANCE CRITERIA

224 nm
WBCIL ACHIEVED

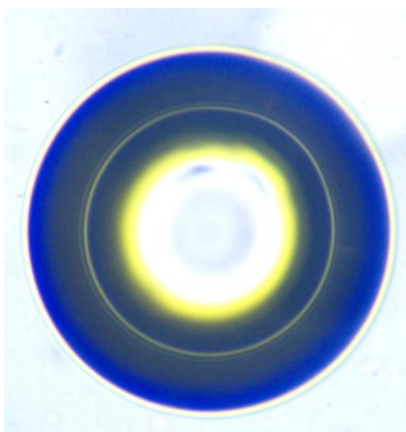


Figure 4A: Microscopic image of a liposomal Iron

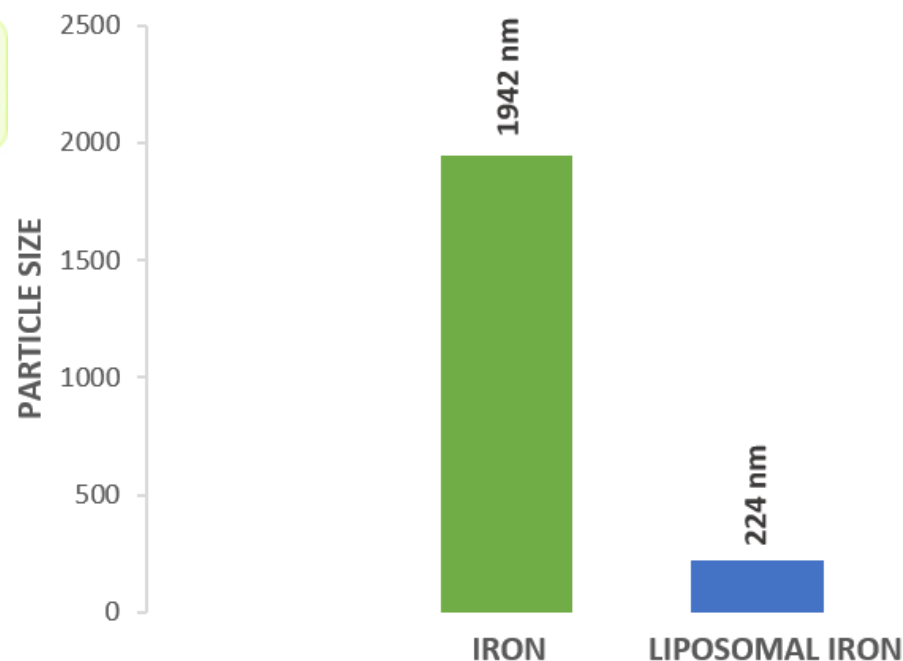


Figure 4B: Particle size of Iron API vs Liposomal Iron in solution

KEY ADVANTAGES

- ✓ Increased Cellular Uptake

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

< 0.50

ACCEPTANCE CRITERIA

0.2799

WBCIL ACHIEVED PDI

KEY ADVANTAGES

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

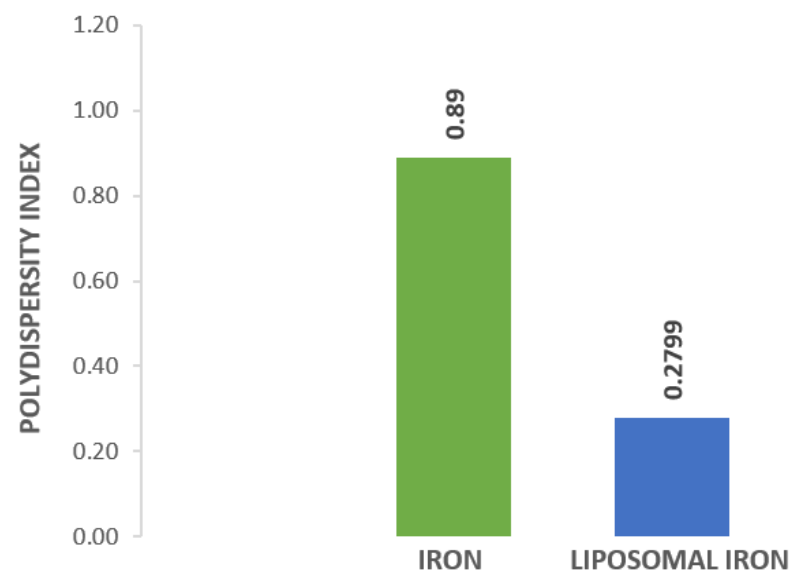
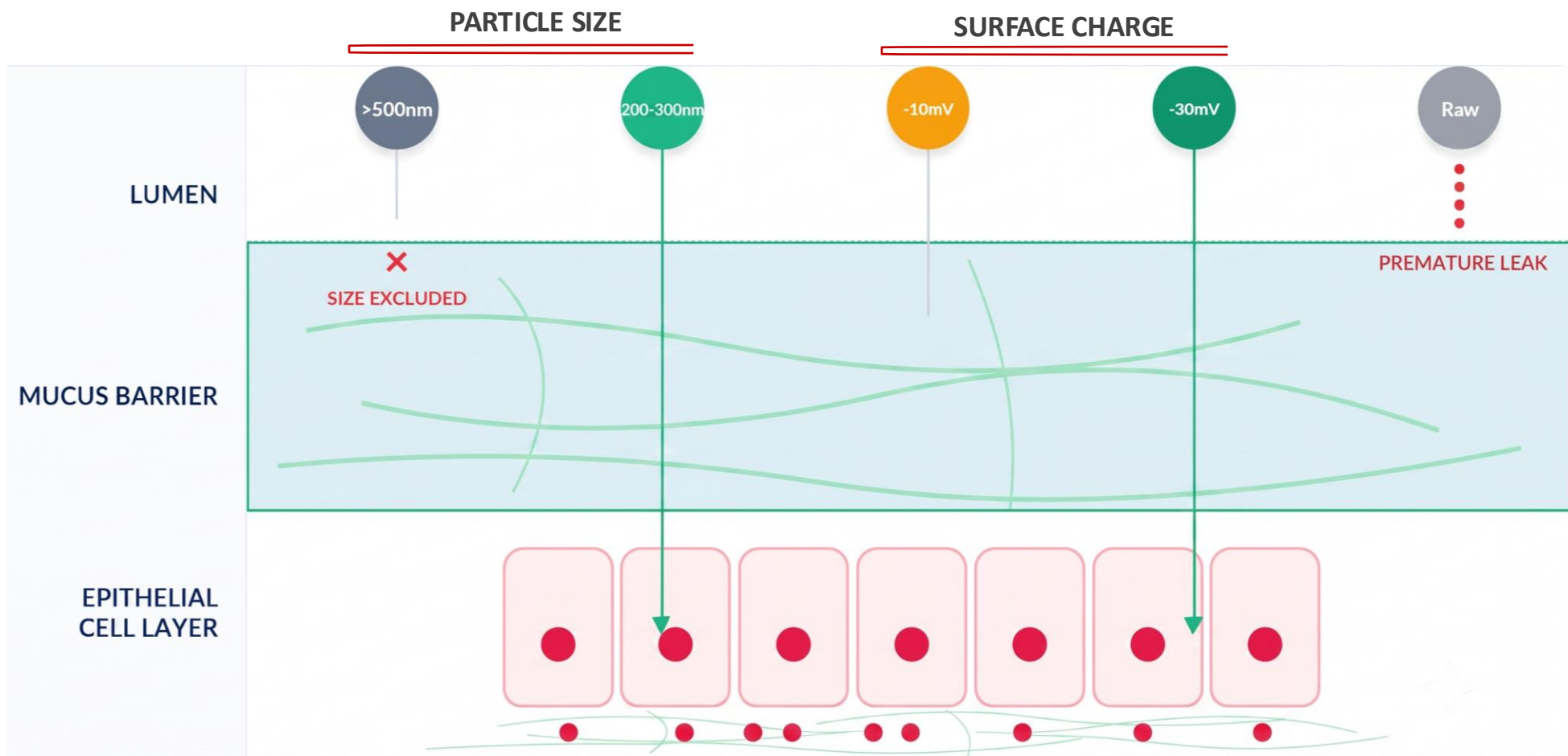


Figure 5: Polydispersity Index (PDI) of Iron API vs Liposomal Iron in solution

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



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

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

Feature Observed	Raw Iron	Empty Liposome	Liposomal Iron
Lipid Bilayer Signal	Absent	Present	Present & Verified
Active Peak (Fe-O)	Sharp & Crystalline	Absent	Modified & Broadened
Structure Proof	Iron Powder	Empty liposome	Iron Embedded in Lipid Matrix



The "Fingerprint" Region ($1200\text{--}500\text{ cm}^{-1}$) of liposomal iron shows a merged pattern, indicating that the Iron is fully encapsulated within the liposome

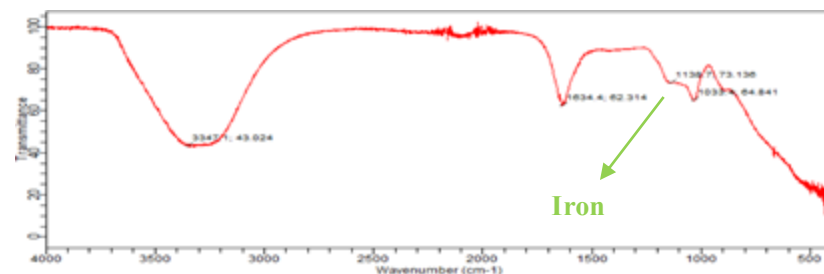


Figure 6A: FTIR Spectra of Iron API

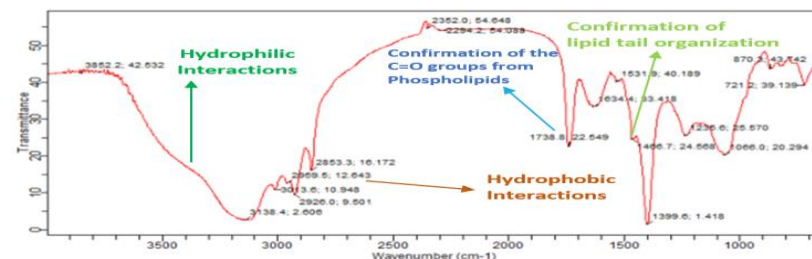


Figure 6B: FTIR Spectra of Empty Liposome

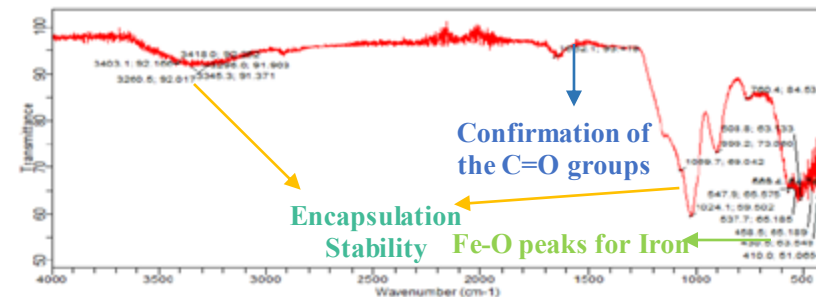


Figure 6C: FTIR Spectra of Liposomal Iron

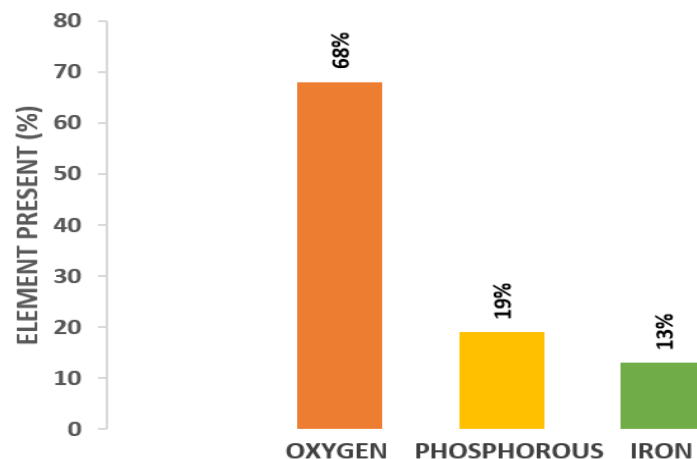
The Surface Proof: Energy-Dispersive X-ray Spectroscopy

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

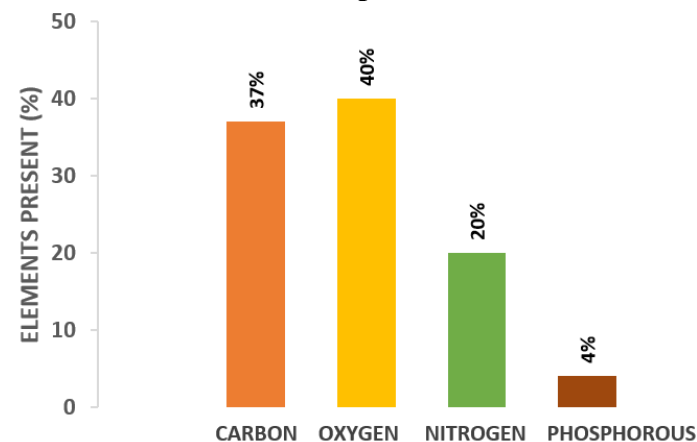
Element Detected	Standard Iron	Liposomal Iron
Iron (Ferric Pyrophosphate)	Present	Absent (Surface)
Liposome (C, N)	Absent	Present (Lipid Bilayer)

✓ **CONCLUSION: Successful Encapsulation of Active Iron**
ensures zero metallic taste

7A: EDAX of Iron Pyrophosphate



7B: EDAX of Liposomal Iron



Scanning Electron Microscope (SEM) Image of Liposomal Iron

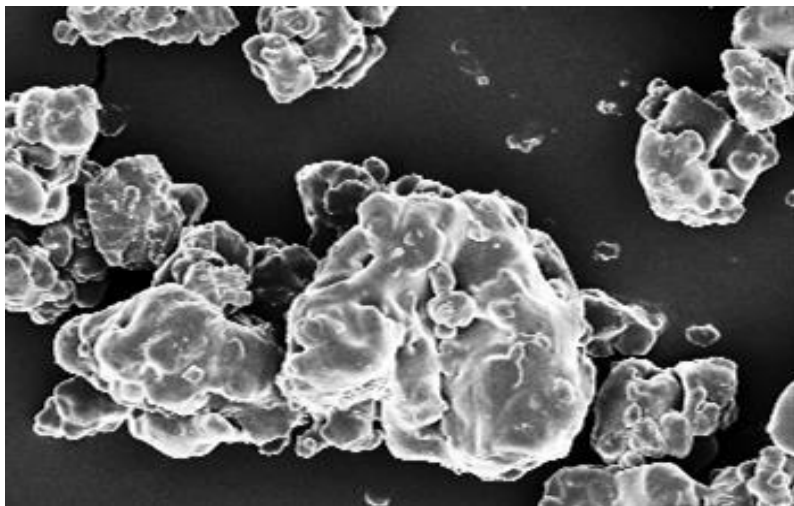


Figure 8A: SEM image of Iron API

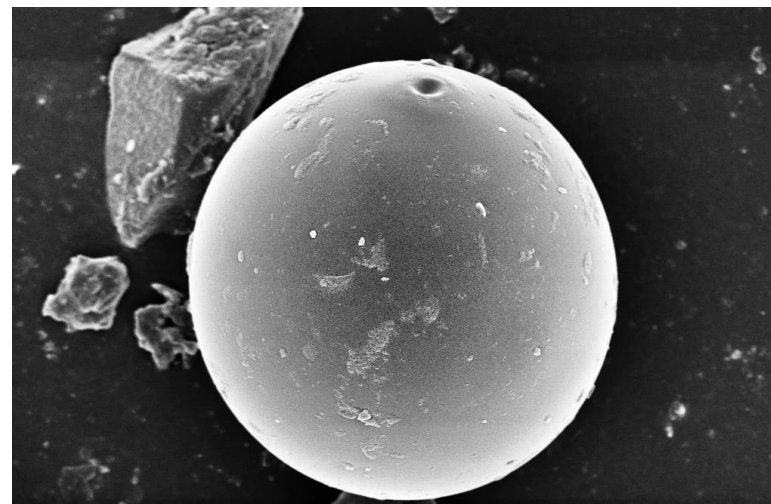


Figure 8B: SEM image of Liposomal Iron

WBCIL Liposomes are perfectly smooth spheres. This morphology:

- Enhances overall stability
- Ideal for efficient drug delivery

The Accelerated Stability Test

We tested our **liposomal iron** under Extreme Conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ Humidity) for 6 months to see if it would leak or lose power, resulting in a decrease in iron content

98.38%
ACTIVE RETENTION

1.48%
TOTAL ASSAY LOSS



Proven Shelf-Life in Extreme Conditions

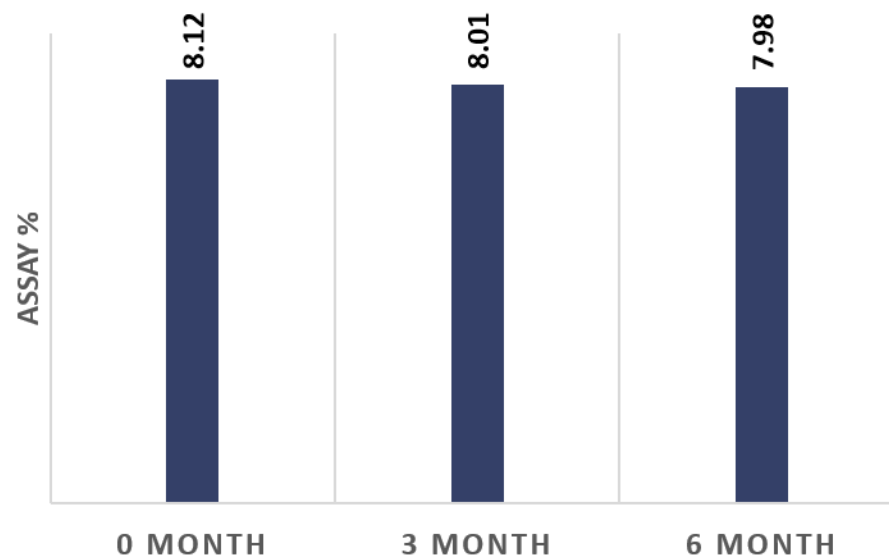


Figure 9: Determination of the Assay% of Liposomal Iron observed under accelerated condition ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ Humidity) for 6 months

The Real-Time Stability Test

Under normal shelf conditions ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $65\% \pm 5\%$ Humidity) for 36 months, the **liposomal iron** remains even more resilient, ensuring the patient gets the full dose every time.

97.29%

ACTIVE RETENTION

2.71%

TOTAL ASSAY LOSS



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

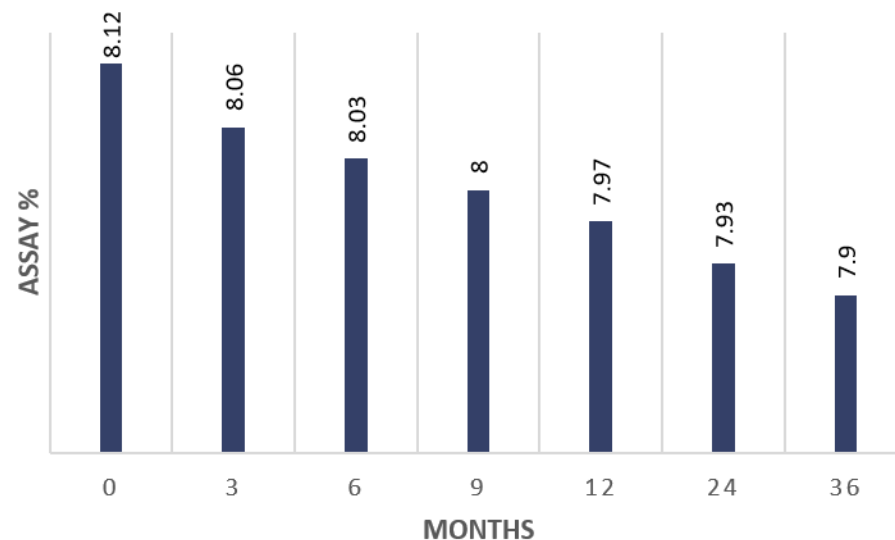


Figure 10: Determination of the Assay% of Liposomal Iron observed under real-time condition ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $65\% \pm 5\%$ Humidity) for 36 months

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)

Raw Iron Powder

150 - 170°C

Empty Liposome

136.85°C

Liposomal Iron

180 - 240°C



Superior Heat Resistance for Manufacturing

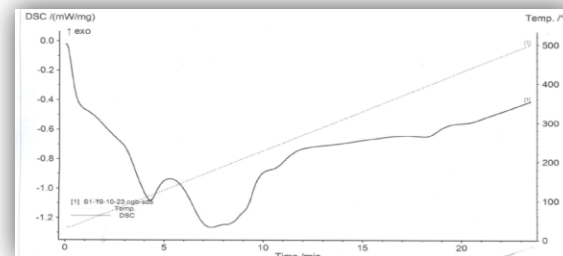


Figure 11A: DSC Thermogram of Iron API

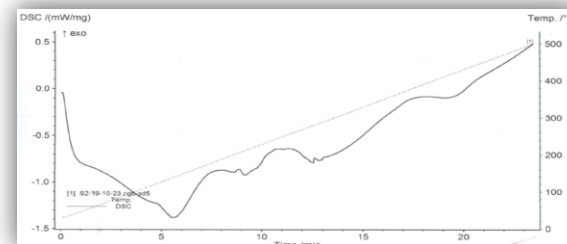


Figure 11B: DSC Thermogram of Empty Liposome

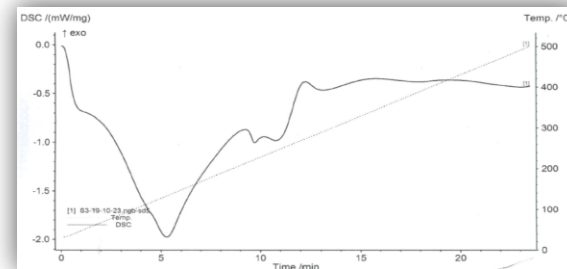


Figure 11C: DSC Thermogram of Liposomal Iron

Thermogravimetric Analysis (TGA): The Heat Resistance Test

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

Final Mass Residue at 800°C (%)

Iron Pyrophosphate

53.0%

Empty Liposome

1.5%

Liposomal Iron

45.0%



TGA shows overlapping iron and lipid transitions, with iron surviving intense heat.

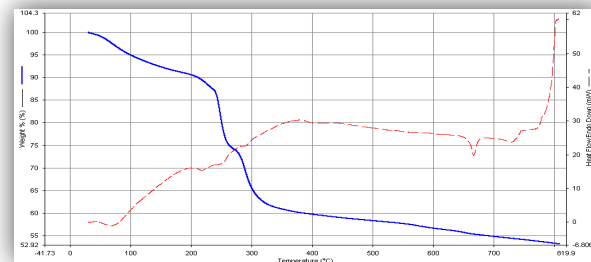


Figure 12A: TGA Thermogram of Iron API

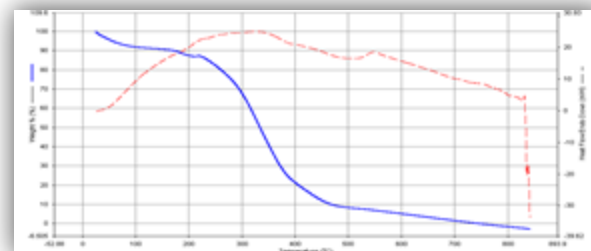


Figure 12B: TGA Thermogram of Empty Liposome

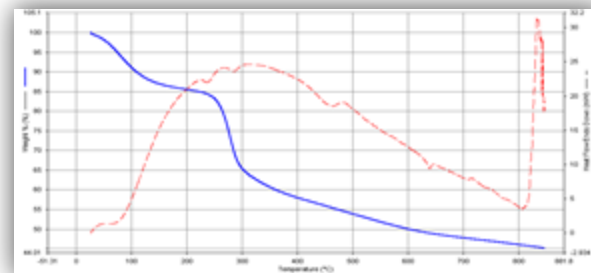


Figure 12C: TGA Thermogram of Liposomal Iron

Summary

1. Encapsulation Efficiency & Capacity

a. Encapsulation Efficiency:	80%	Minimal loss & taste masking
b. Loading Capacity:	71%	Efficient dosing, lower cost

2. Particle Characteristics & Stability

a. Zeta Potential:	-31 mV	Liposomal stability
b. Particle Size:	224 nm	Improved cellular uptake
c. PDI:	0.24	Uniform, stable liposomes

3. Structural & Chemical Confirmation

a. FTIR:	Spectral shift	Iron integrated, not physically mixed
b. EDAX:	No surface iron	Iron 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 T _m	Ensures thermal stability

THANK YOU

THANK YOU