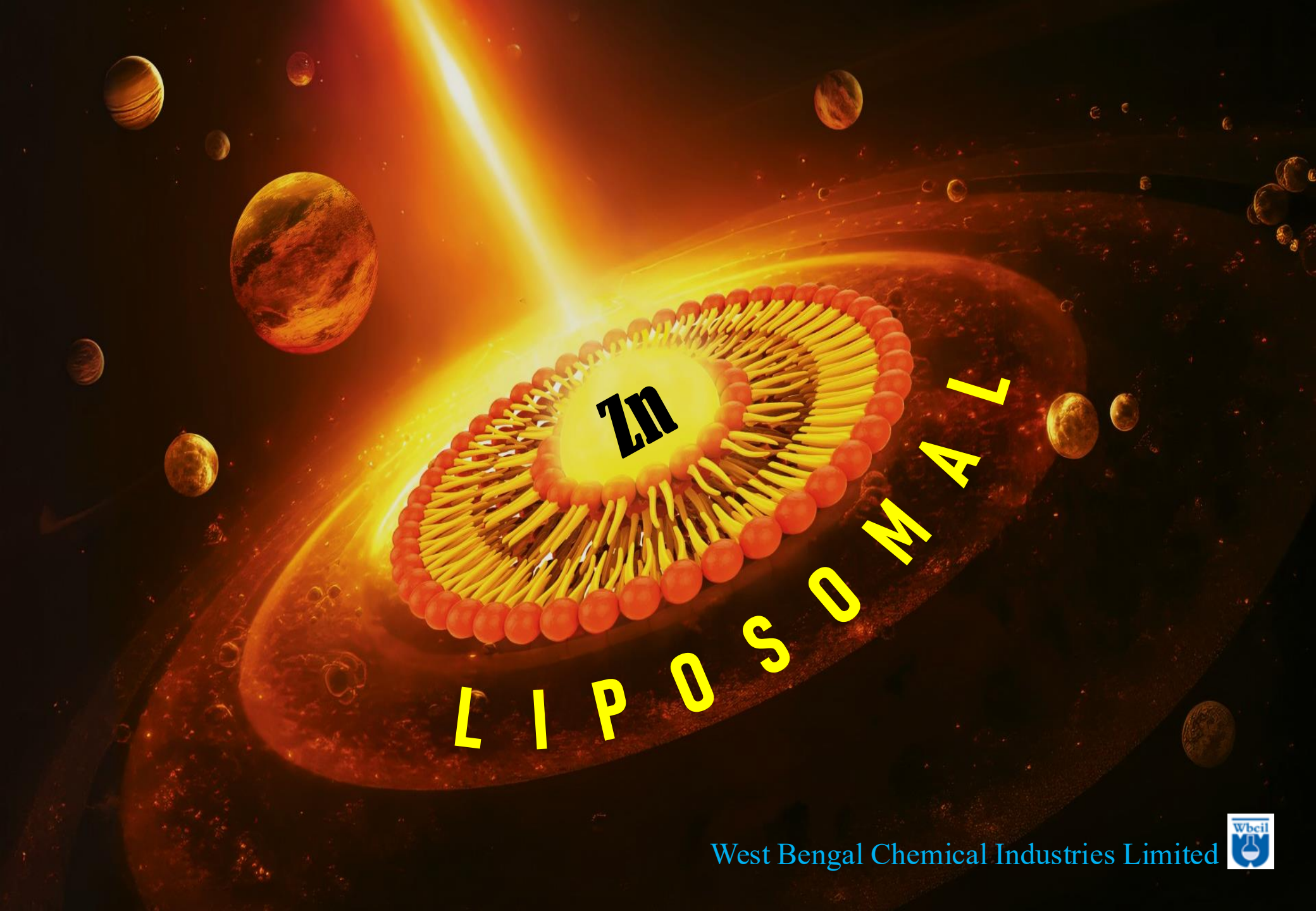




LIPOSOMAL

West Bengal Chemical Industries Limited



INDEX

A USA FDA-Aligned Framework for Quality & Stability Determination

<i>Parameters</i>	<i>Page No.</i>
1. Encapsulation Efficiency & Capacity	
a. Encapsulation Efficiency	4
2. Particle Characteristics & Stability	
a. Zeta Potential	5
b. Particle Size	6
c. PDI	7
3. Structural & Chemical Confirmation	
a. FTIR	9
b. EDAX	10
c. SEM	11
4. Thermal Stability & Integrity	
a. Leakage & Stability	12-13

Challenges with Standard Zinc



Absorption Competition

High intakes of iron and calcium can compete with zinc for absorption, reducing its bioavailability.



GI Intolerance

High-dose zinc salts may cause GI discomfort and a metallic aftertaste.



Dietary Roadblocks

Dietary phytates bind zinc, limiting its absorption.

WBCIL Liposome: The Guarantee of Purity

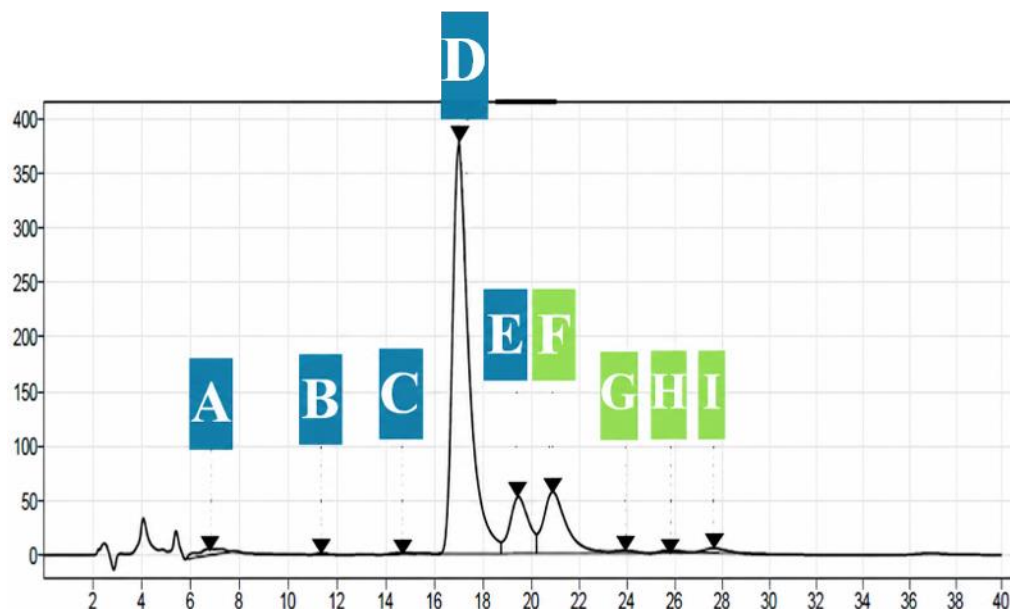


Figure 1 –The chromatogram of a phospholipid constituting a liposome

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

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



Stronger Shells & Cleaner Product

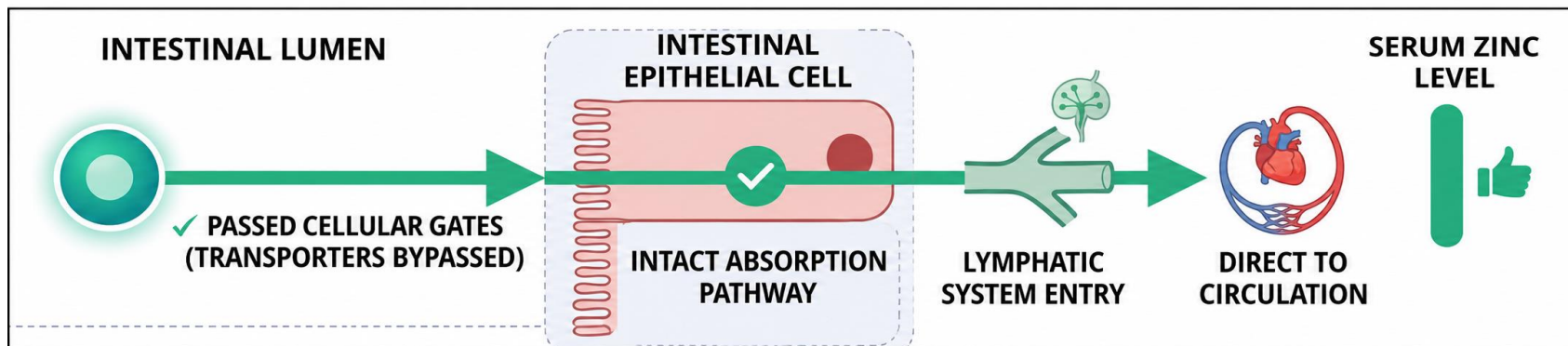
>90% purity ensures liposomal stability
and patient safety by minimising
unwanted lipids



WBCIL Achieved

>94% phospholipid purity with > 90%
PC content

Bypassing Natural Barriers



Bypassing Transporters

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 Zinc avoids liver first-pass metabolism, elevating serum Zinc 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

82.80% Achieved

WBCIL PROPRIETARY PROCESS

KEY ADVANTAGES

- ✓ Improves Bioavailability
- ✓ Prevents Gastric Irritation
- ✓ Better Nutrient Retention
- ✓ Boosts Patient Compliance

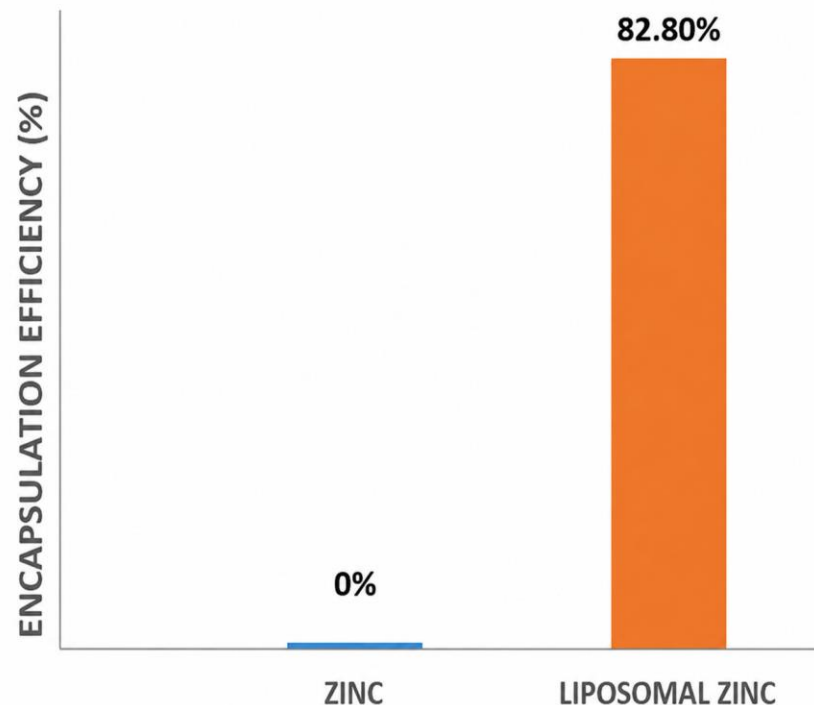


Figure 2: Encapsulation efficiency of Liposomal Zinc

Dynamic Light Scattering Analysis of Liposomal Zinc

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

< -25 mV

ACCEPTANCE CRITERIA

-40.79 mV

WBCIL ACHIEVED ZP

KEY ADVANTAGES

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

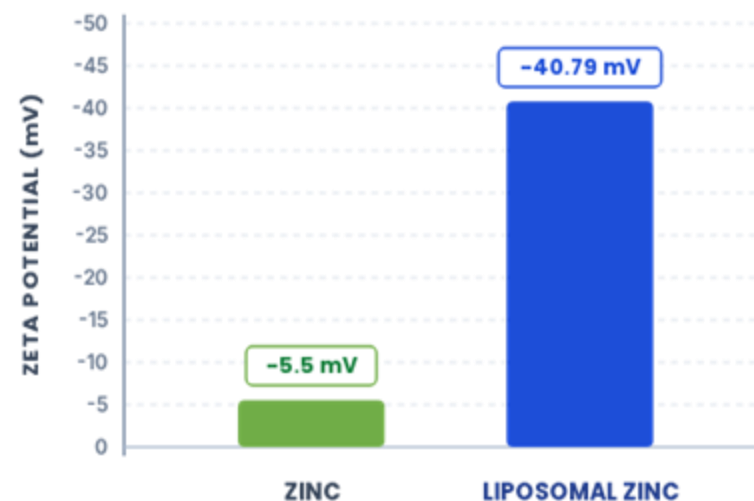
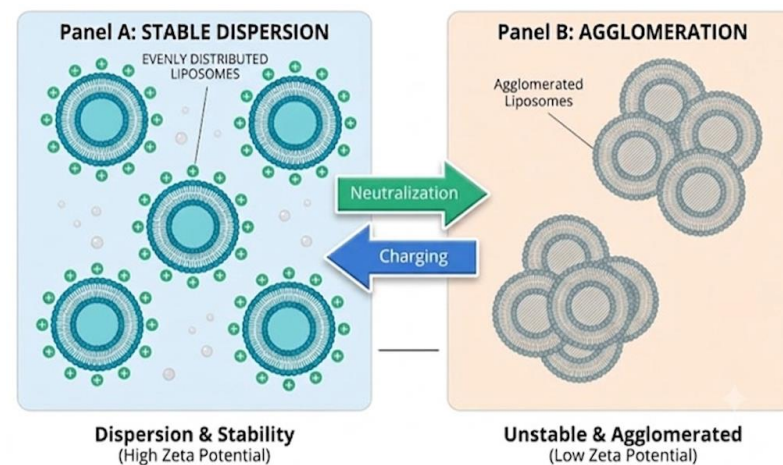


Figure 3: Determination of Zeta Potential

B. Particle Size determination

≤ 300 nm
ACCEPTANCE CRITERIA

203.10 nm
WBCIL ACHIEVED

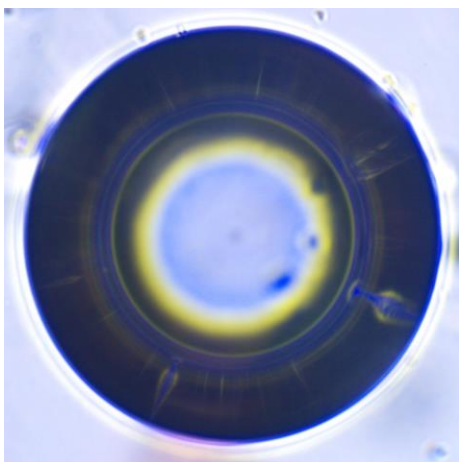


Figure 4A: Microscopic image of a liposomal Zinc

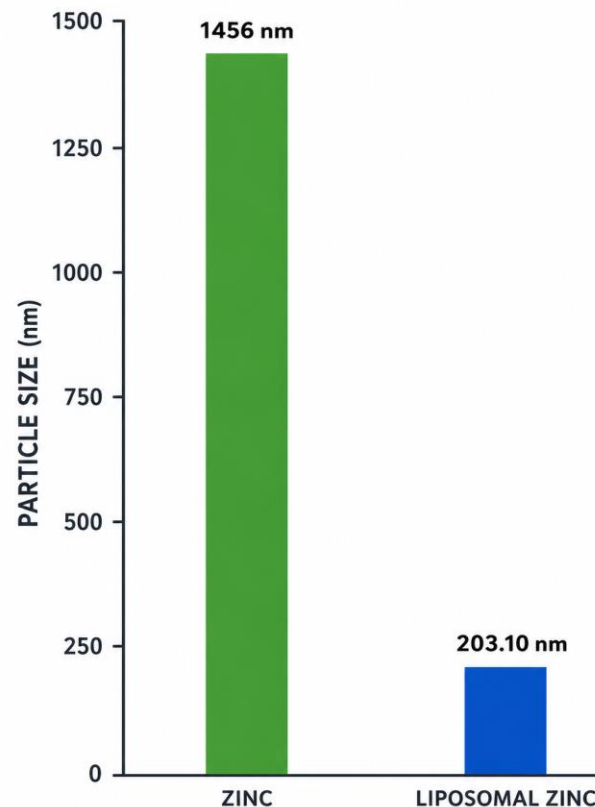


Figure 4B: Particle size of Zinc API vs Liposomal Zinc in solution

KEY ADVANTAGES

✓ Increased Cellular Uptake

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

< 0.50

ACCEPTANCE CRITERIA

0.33

WBCIL ACHIEVED PDI

KEY ADVANTAGES

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

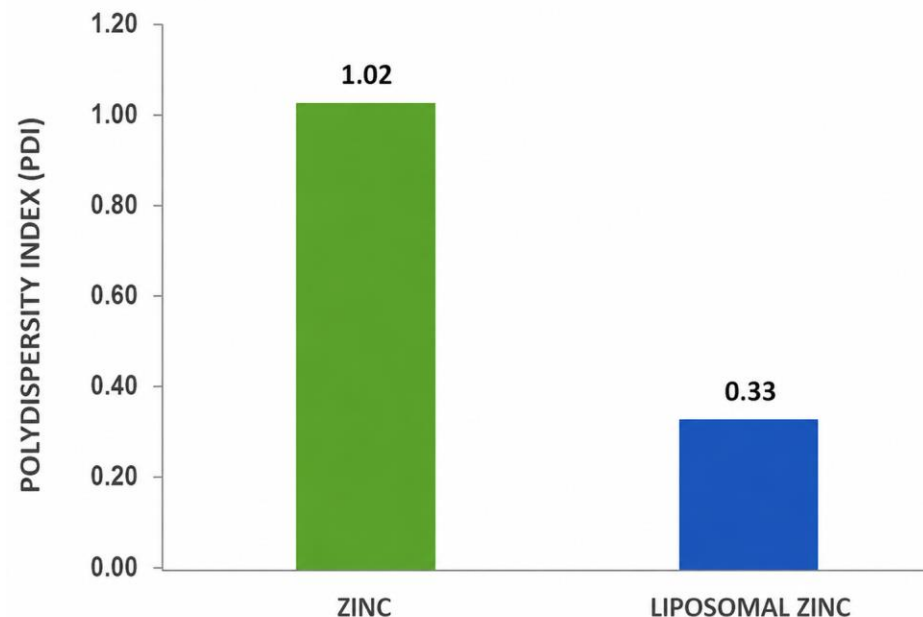
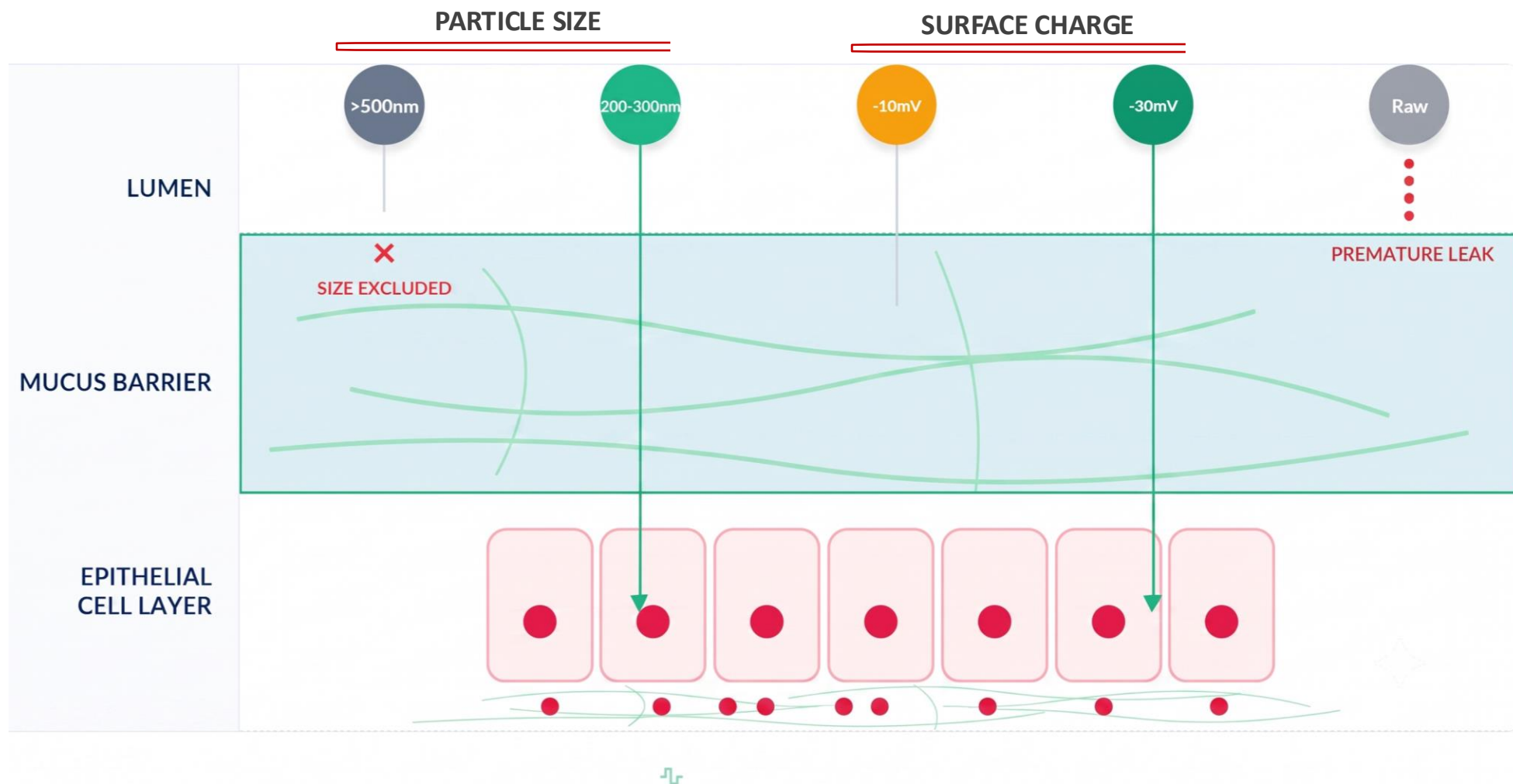


Figure 5: Polydispersity Index (PDI) of Zinc API vs Liposomal Zinc in solution

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



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

 **The "Fingerprint" Region (400–600 cm^{-1})** of liposomal Zinc shows a merged pattern, indicating that the Zinc is fully encapsulated within the liposome



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

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

Element Detected	Standard active Zinc	WBCIL Liposomal Zinc
Zinc	Present	Absent (Surface)
Liposome (C, N, and Phosphorus)	Absent	Present (Lipid Bilayer)

CONCLUSION: Successful Encapsulation of Active Zinc ensures zero metallic taste

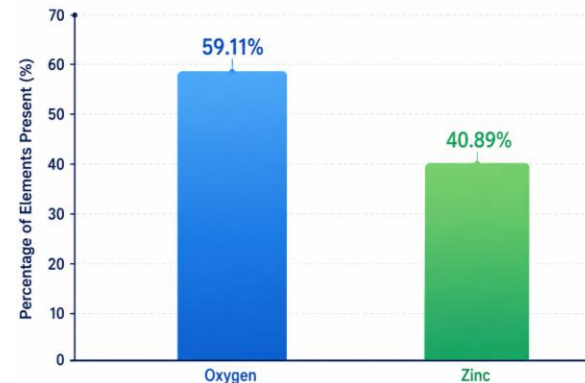


Figure 8A: EDAX of Zinc Oxide

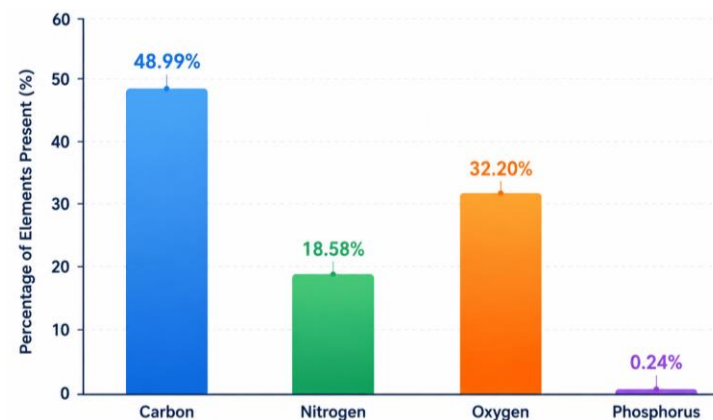


Figure 8B: EDAX of Liposomal Zinc

Scanning Electron Microscope (SEM) Image of Liposomal Zinc

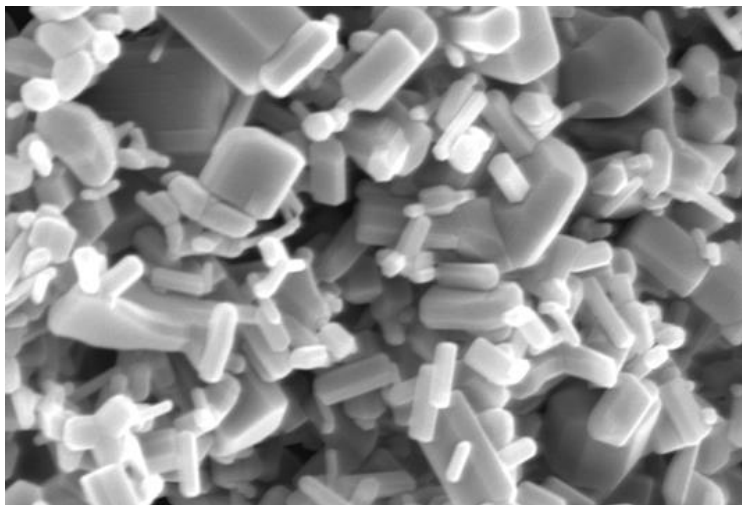


Figure 9A: SEM image of Zinc API

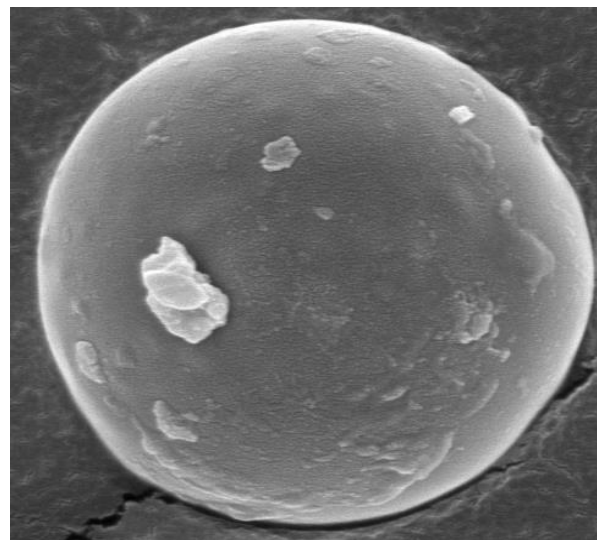


Figure 9B: SEM image of Liposomal Zinc

WBCIL Liposomes are perfectly smooth spheres. This morphology:

- Enhances overall stability
- Ideal for efficient drug delivery

The Accelerated Stability Test

We tested our **liposomal Zinc** 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 Zinc content

98%

ACTIVE RETENTION

2%

TOTAL ASSAY LOSS



OUTCOME: Complete structural preservation ensures longer shelf-life

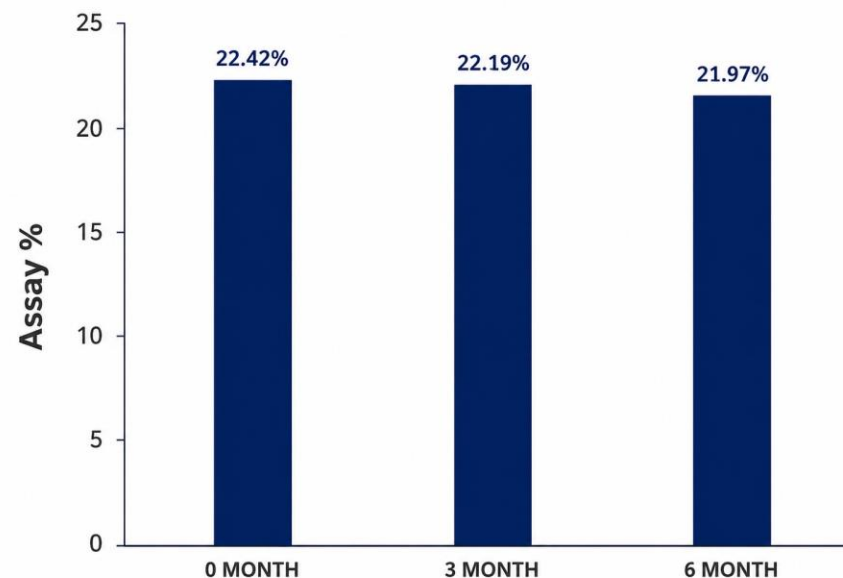


Figure 9: Determination of the Assay% of Liposomal Zinc observed under accelerated condition ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ Humidity) for 6 months

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 Zinc** remains even more resilient, ensuring the patient gets the full dose every time.

97.55%

ACTIVE RETENTION

2.45%

TOTAL ASSAY LOSS



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



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

Summary

1. Encapsulation Efficiency & Capacity

a. Encapsulation Efficiency:	82.80%	Minimal loss & taste masking
------------------------------	--------	------------------------------

2. Particle Characteristics & Stability

a. Zeta Potential:	-40.79 mV	Liposomal stability
b. Particle Size:	203.10 nm	Improved cellular uptake
c. PDI:	0.33	Uniform, stable liposomes

3. Structural & Chemical Confirmation

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

4. Thermal Stability & Integrity

a. Leakage & Stability:	< 3% leakage	Long-term product stability
-------------------------	--------------	-----------------------------

THANK YOU

THANK YOU