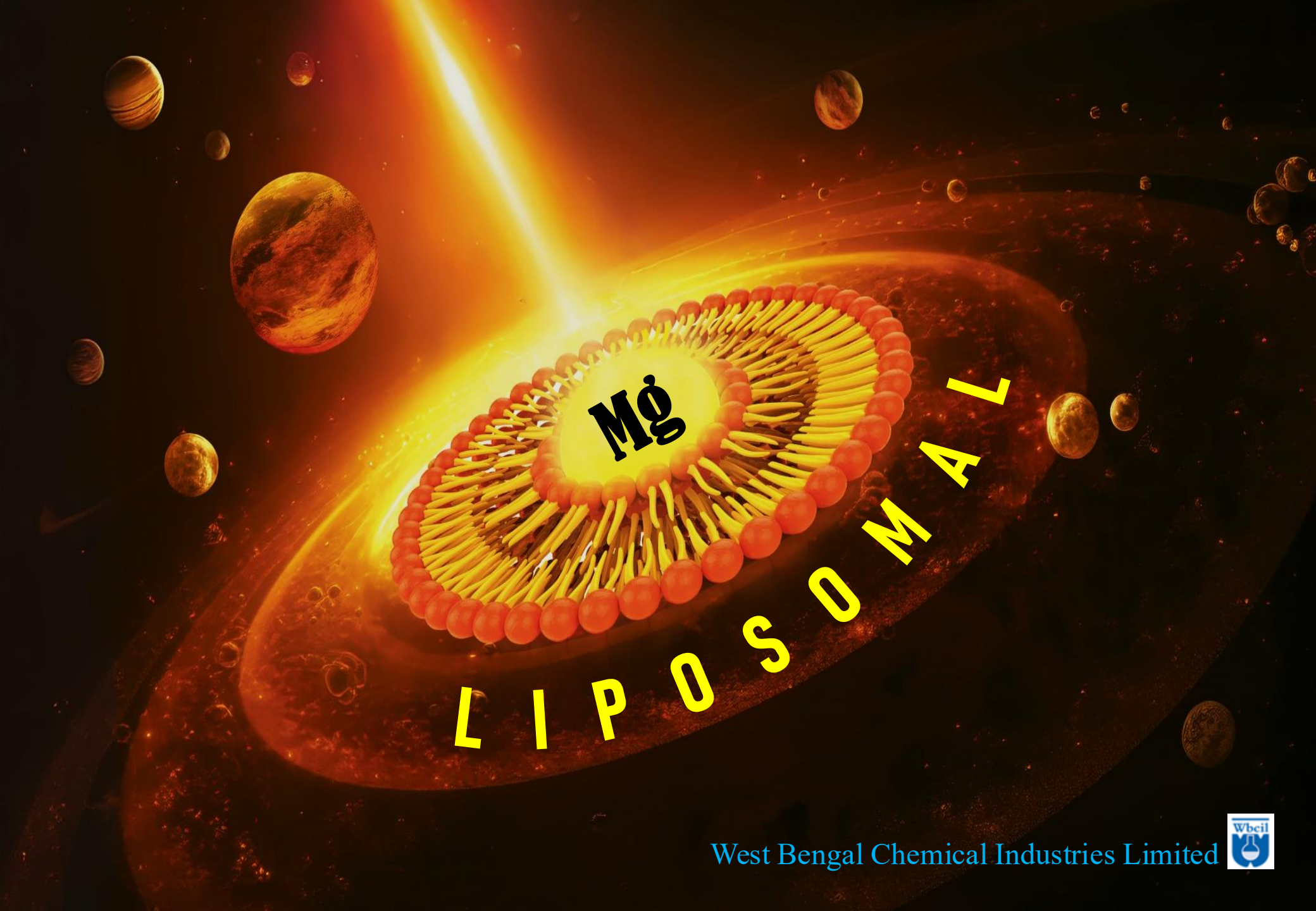




Mg

LIPOSOMAL

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 Magnesium



Limited Bioavailability

Oral bioavailability is limited to only 4%



Rapid degradation

Magnesium salts lose their stability in the gastric environment



Systemic GI Distress

High elemental doses induce bloating and osmotic diarrhea, compromising patient compliance

WBCIL Liposome: The Guarantee of Purity

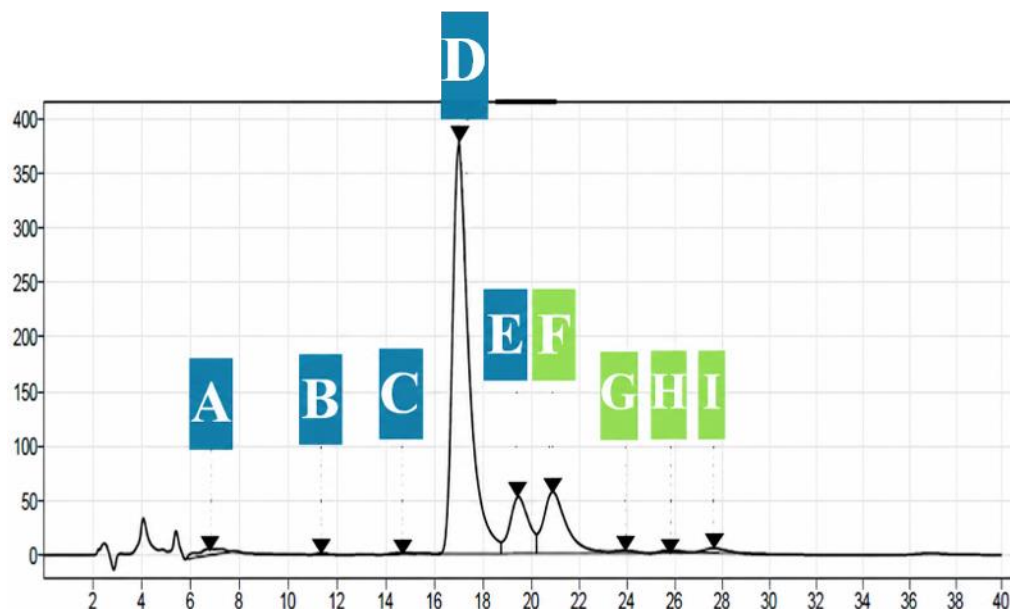


Figure 1 –The chromatogram of a phospholipid constituting a liposome

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

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



Stronger Shells & Cleaner Product

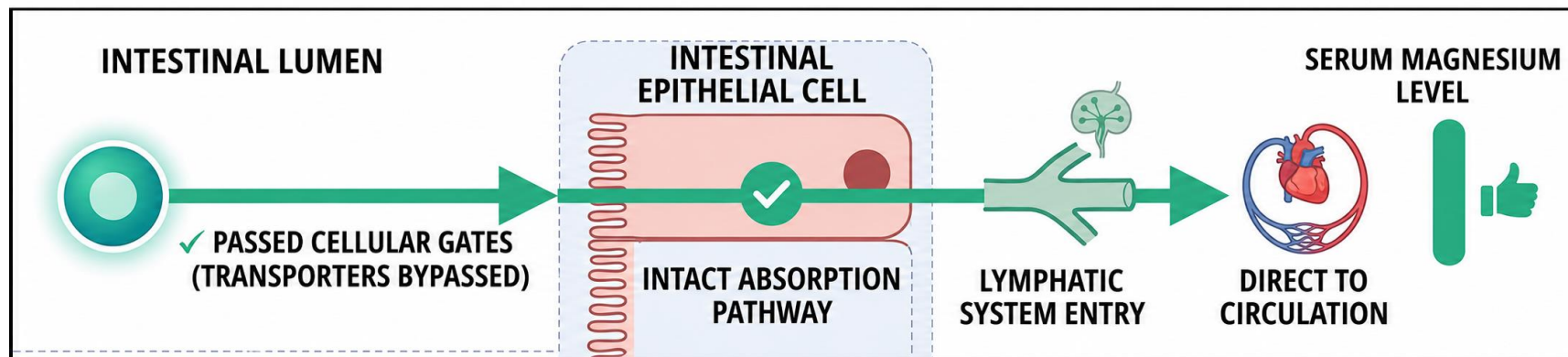
>90% purity ensures liposomal stability
and patient safety by minimising
unwanted lipids



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 Mg avoids liver first-pass metabolism, elevating serum Mg 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

80.49% Achieved

WBCIL PROPRIETARY PROCESS

KEY ADVANTAGES

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

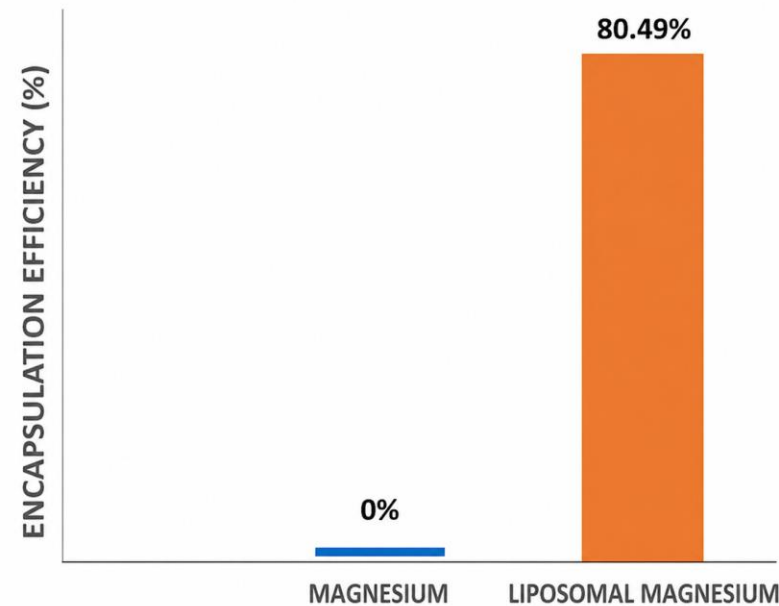


Figure 2: Encapsulation efficiency of Liposomal Magnesium

Dynamic Light Scattering Analysis of Liposomal Magnesium

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

< -25 mV
ACCEPTANCE CRITERIA

-35 mV
WBCIL ACHIEVED ZP

KEY ADVANTAGES

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

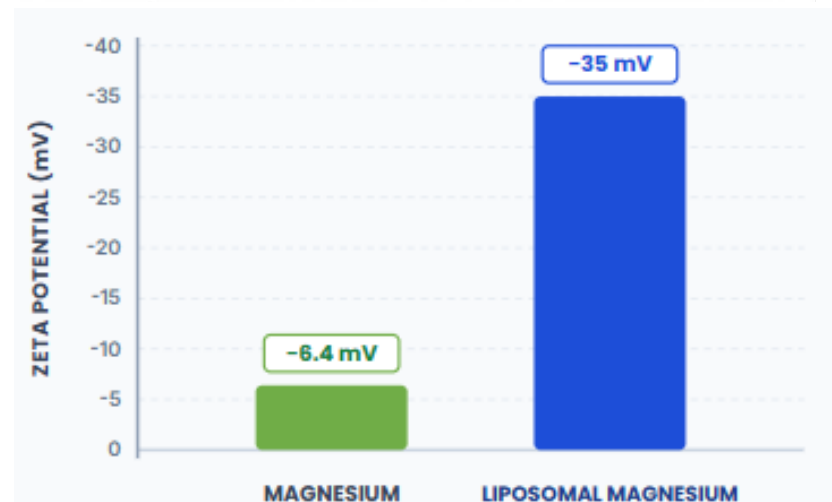
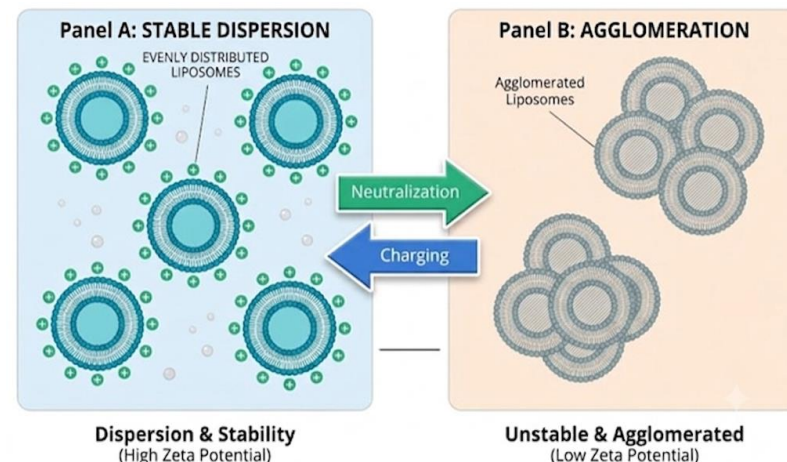


Figure 3: Determination of Zeta Potential

B. Particle Size determination

≤ 300 nm

ACCEPTANCE CRITERIA

212 nm

NANOSCALE SIZE

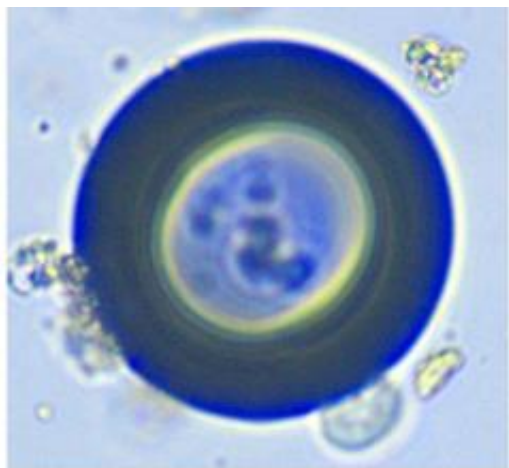


Figure 4: Microscopic image of a liposomal Magnesium

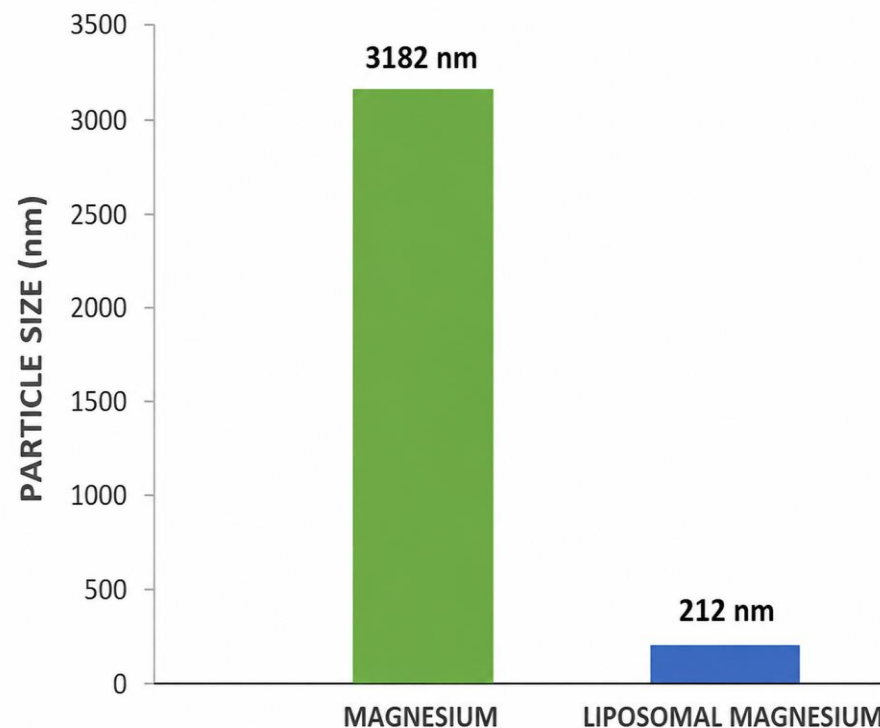


Figure 4A: Particle size of Mg API vs Liposomal Mg in solution

KEY ADVANTAGES

- ✓ Increased Cellular Uptake

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

< 0.50

ACCEPTANCE CRITERIA

0.23

WBCIL ACHIEVED PDI

KEY ADVANTAGES

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

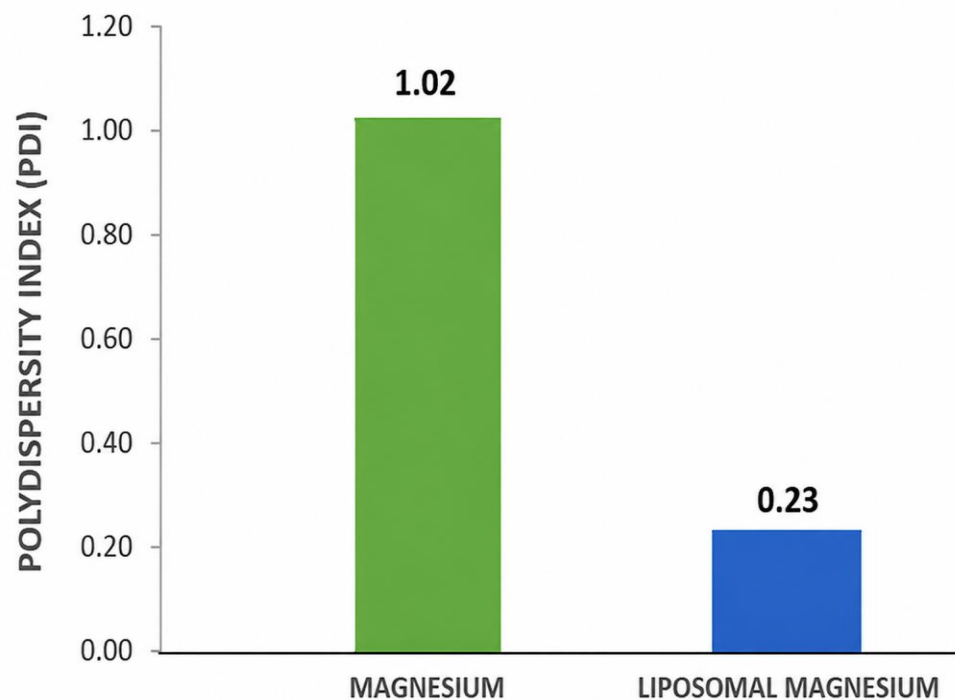
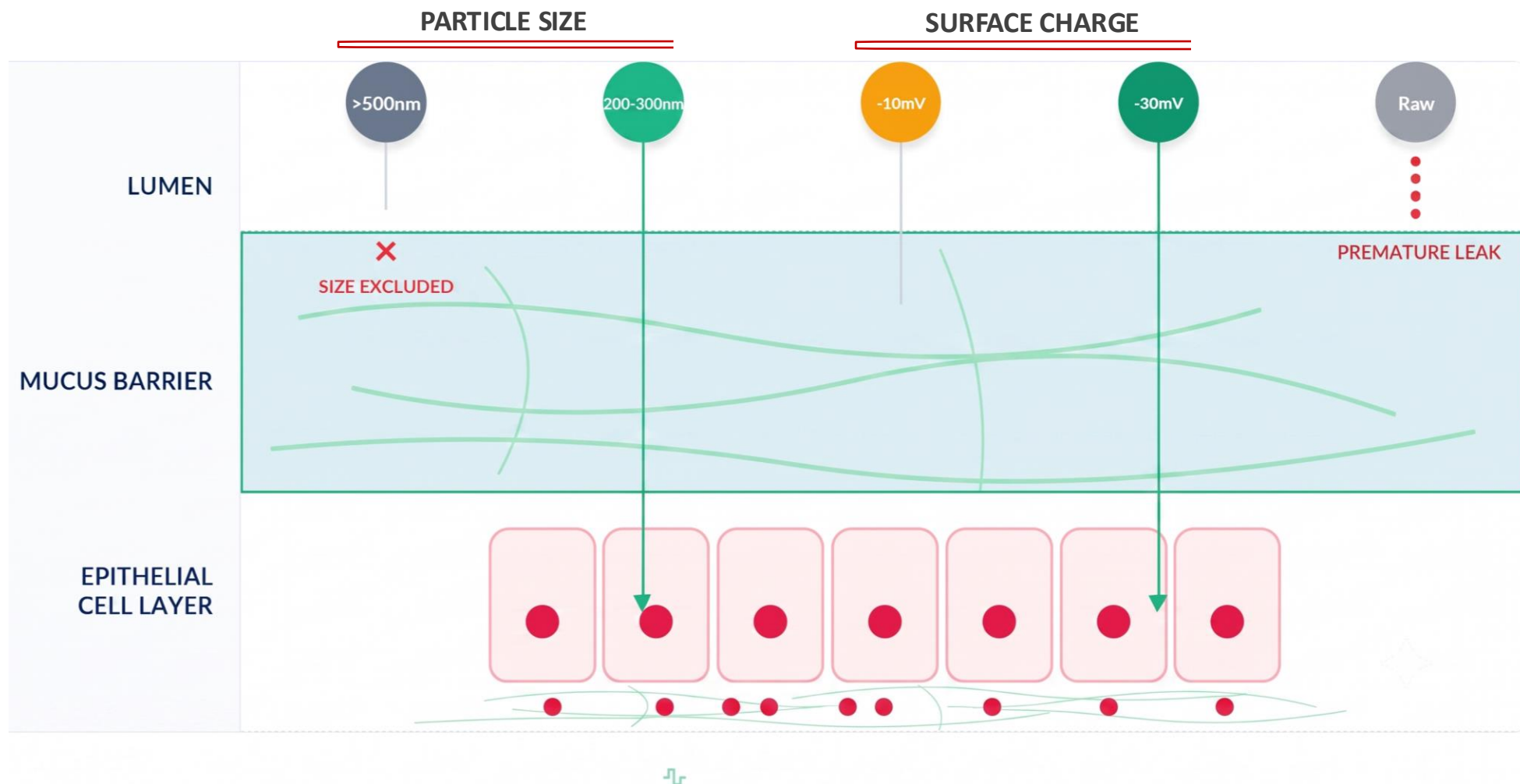


Figure 5: Polydispersity Index (PDI) of Mg API vs Liposomal Mg in solution

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

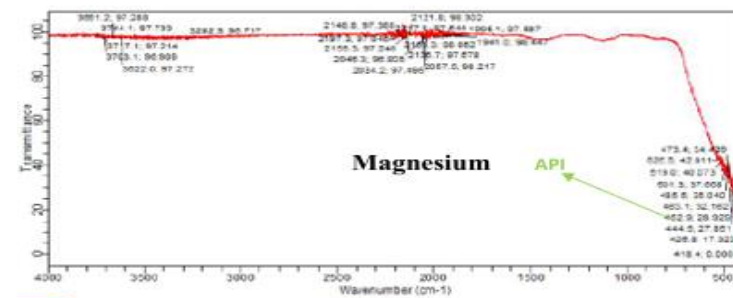


The Fingerprint Test: Fourier Transform Infrared Spectroscopy (FTIR) of Liposomal Magnesium

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

Feature Observed	Raw Mg	Empty Liposome	Liposomal Mg
Lipid Bilayer Signal (2920 & 2853 cm^{-1})	Absent	Present	Present & Verified
Metal –Oxygen signal (418-526 cm^{-1})	Sharp & Crystalline	Absent	Modified & Broadened
Structure Proof	Mg Powder	Empty liposome	Mg Embedded in Lipid Matrix

 **The "Fingerprint" Region (418–526 cm^{-1})** The Metal-Oxygen signal shows shifted, interacting patterns, confirming encapsulation of Magnesium ions within a liposome rather than a simple physical mixture



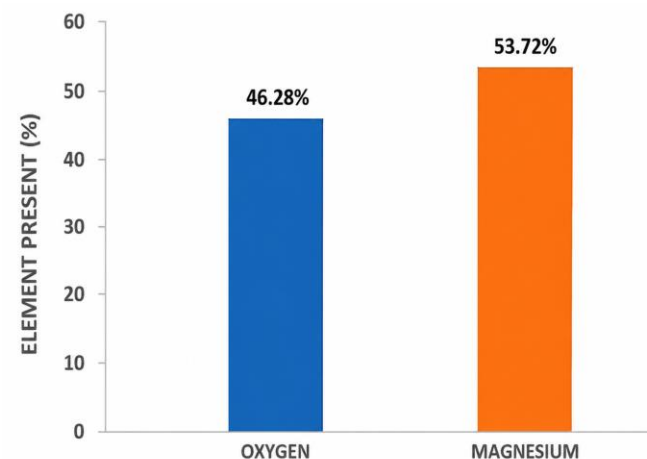
The Surface Proof: Energy-Dispersive X-ray Spectroscopy

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

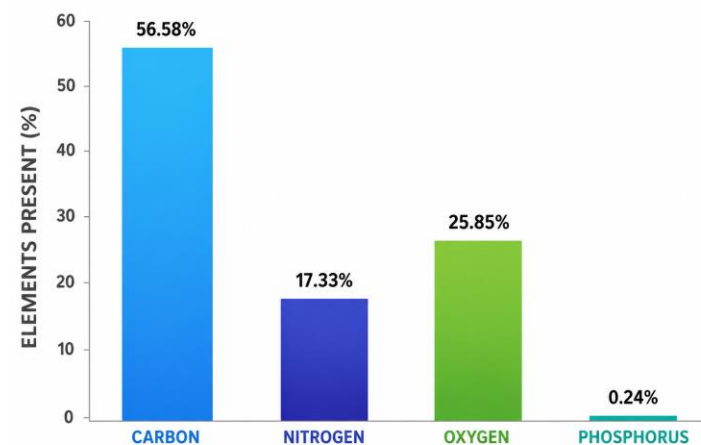
Element Detected	Standard Mg	Liposomal Mg
Magnesium	Present	Absent (Surface)
Carbon, Phosphorous & Nitrogen (Present in lipid)	Absent	Present (Lipid Bilayer)

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

7A: EDAX of Magnesium Oxide



7B: EDAX of Liposomal Magnesium



Scanning Electron Microscope (SEM) Image of Liposomal Magnesium

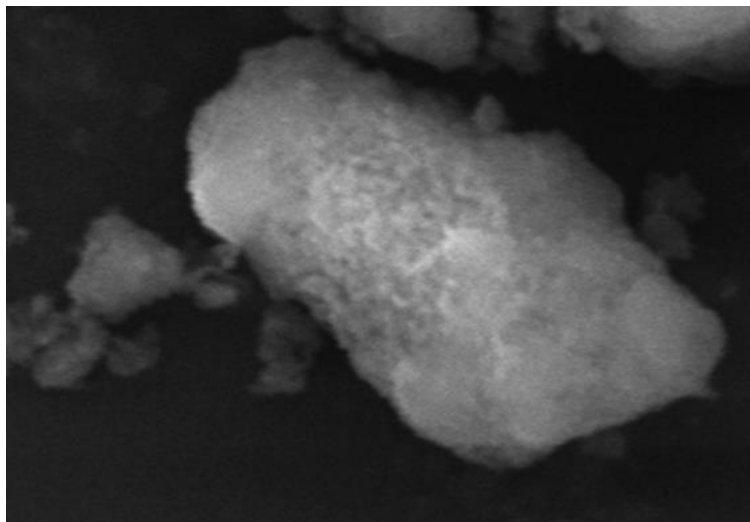


Figure 8A: SEM image of Magnesium API

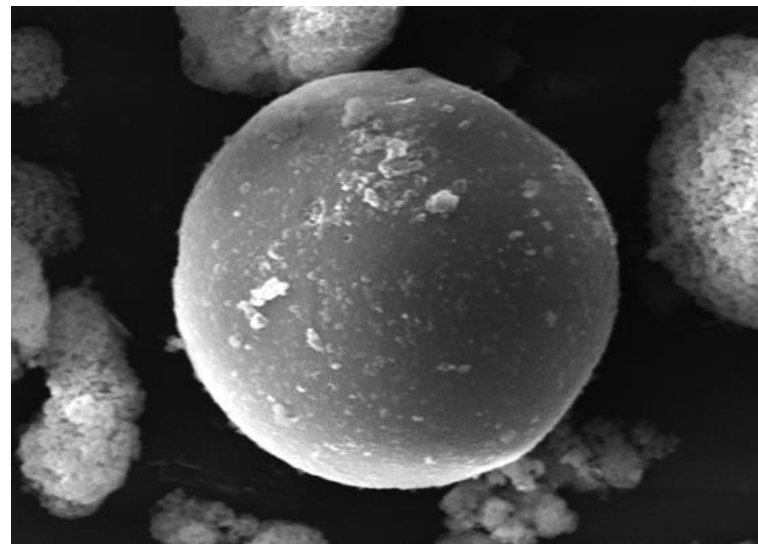


Figure 8B: SEM image of Liposomal Magnesium

WBCIL Liposomes are perfectly smooth spheres. This morphology:

- Enhances overall stability
- Ideal for efficient drug delivery

The Accelerated Stability Test

We tested our **liposomal Magnesium** 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 Magnesium content

99.32%

ACTIVE RETENTION

0.68%

TOTAL ASSAY LOSS



Proven Shelf-Life in Extreme Conditions

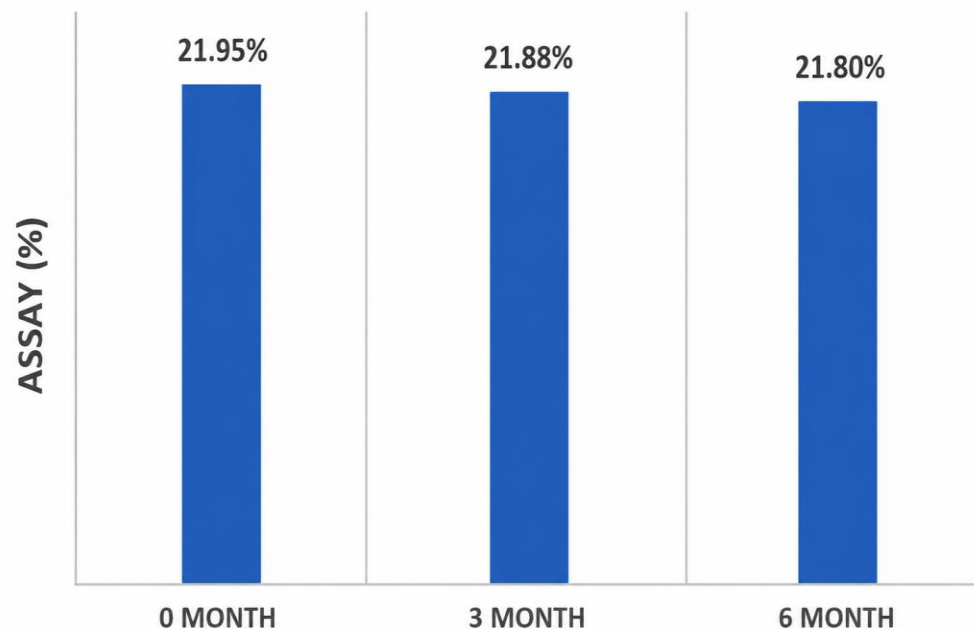


Figure 9: Determination of the Assay% of Liposomal Magnesium observed under accelerated condition ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ Humidity) for 6 months

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

99.22%

ACTIVE RETENTION

1.59%

TOTAL ASSAY LOSS



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



Figure 10: Determination of the Assay% of Liposomal Magnesium 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:

80.49%

Minimal loss & taste masking
Efficient dosing, lower cost

2. Particle Characteristics & Stability

a. Zeta Potential:

-35 mV

Liposomal stability

b. Particle Size:

212 nm

Improved cellular uptake

c. PDI:

0.23

Uniform, stable liposomes

3. Structural & Chemical Confirmation

a. FTIR:

Spectral shift

Mg integrated, not physically mixed

b. EDAX:

No surface Magnesium

Mg 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