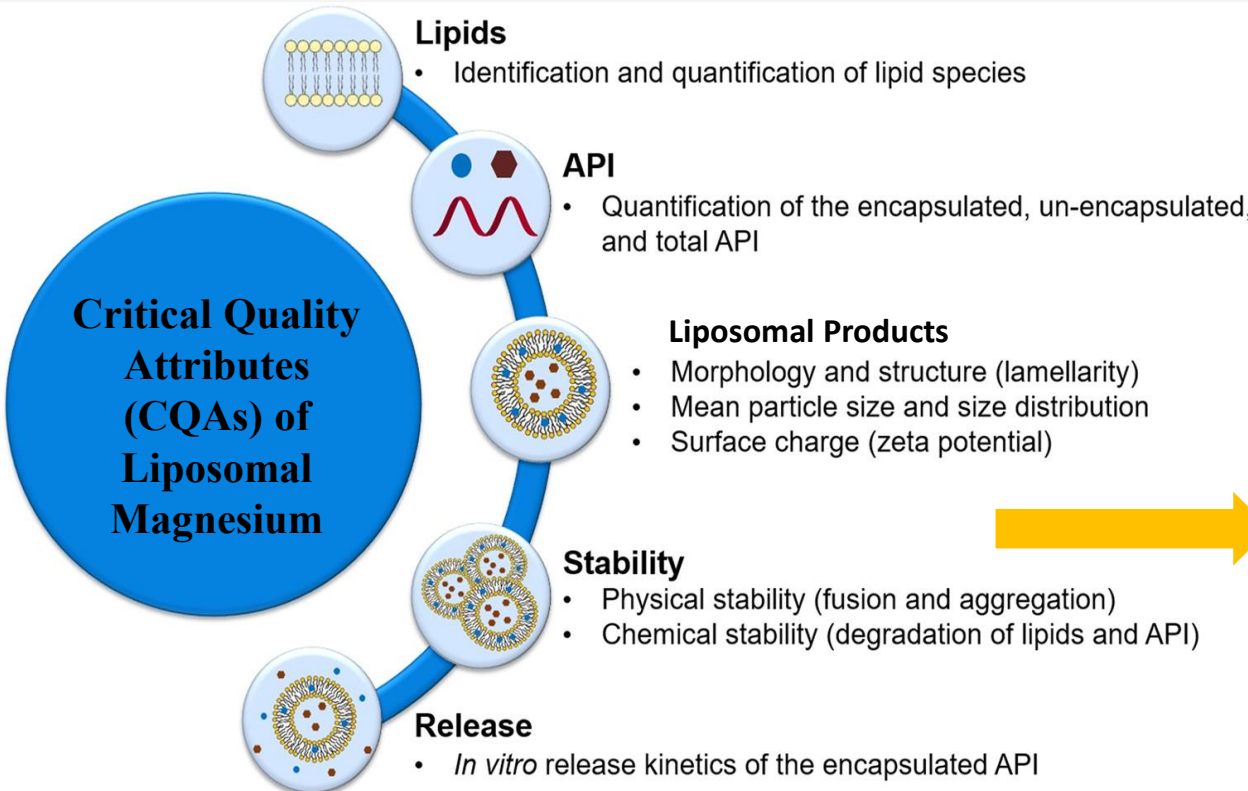




Mg

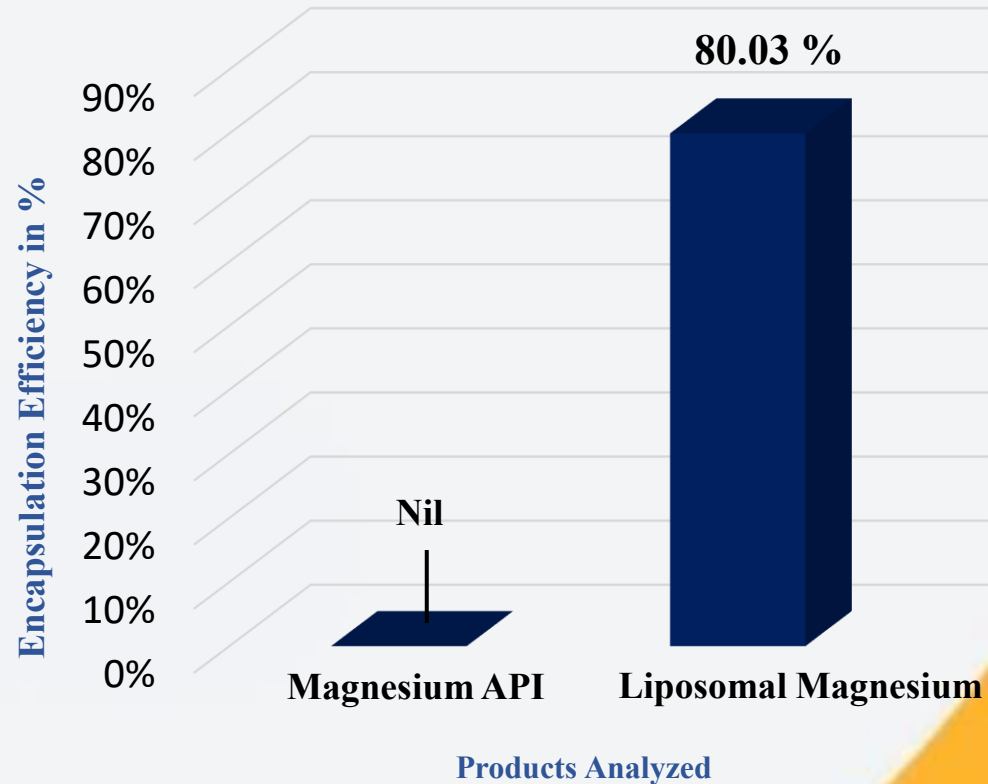
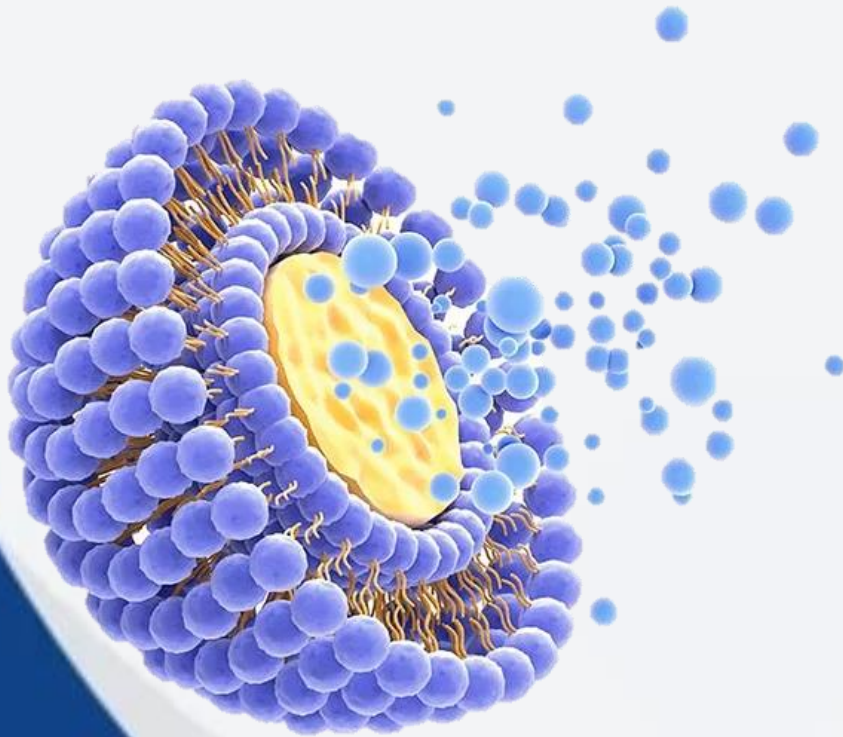
LIPOSO MAL

Summary of Characterizations Performed on Liposomal Magnesium



1. *Encapsulation efficiency of Liposomal Magnesium*
2. *Analysis of particle size and uniformity of Liposomal Magnesium using DLS*
3. *Behavior of Liposomal Magnesium particles in liquid medium using DLS Zeta-sizer*
4. *FTIR analysis of Liposomal Magnesium composition*
5. *Elemental analysis of Liposomal Magnesium*
6. *Morphology analysis of Magnesium Liposomes using SEM*
7. *Analysis of Magnesium leakage from Liposomes*
8. *Stability analysis of Liposomes at 105° C temperatures*
9. *Mineral Loading Capacity*

1. Encapsulation Efficiency of 22.25% Liposomal Magnesium



❖ Acceptance criteria:

- Assay : **22% - 23%**
- Encapsulation efficiency : **NLT 70%**

Encapsulation Efficiency measured by validated titrimetric analytical data

- Liposomal encapsulation ensures **80.03% efficiency**, significantly surpassing the **minimum requirement of 70%**.
- Efficient encapsulation minimizes mineral loss, improving bioavailability and therapeutic efficacy.
- Offers protection against oxidation and gastrointestinal irritation, common with conventional Magnesium forms.

2. Dynamic Light Scattering Analysis of Liposomal Magnesium

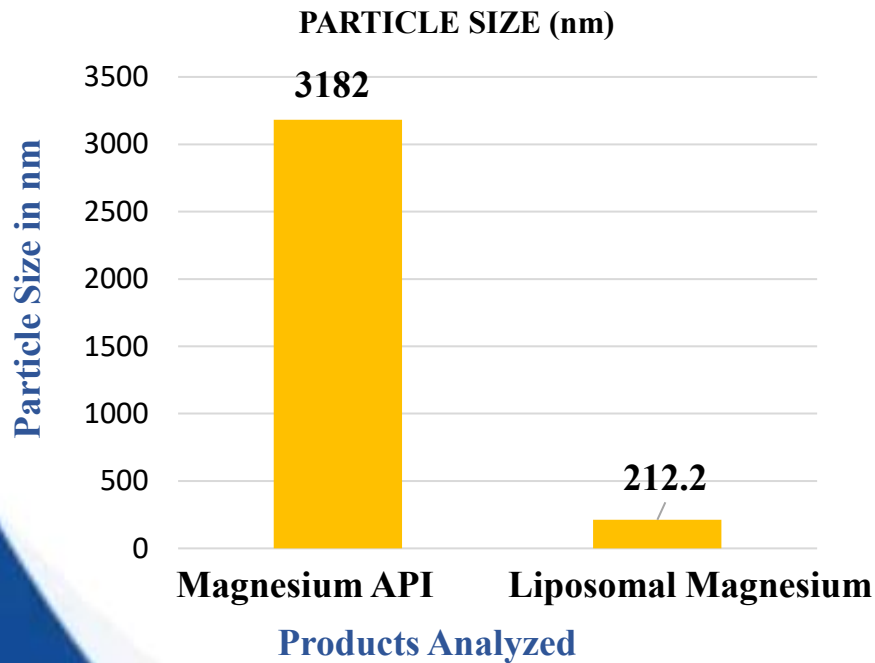


Figure 1 – Chart showing the particle size of Magnesium API with Liposomal Magnesium

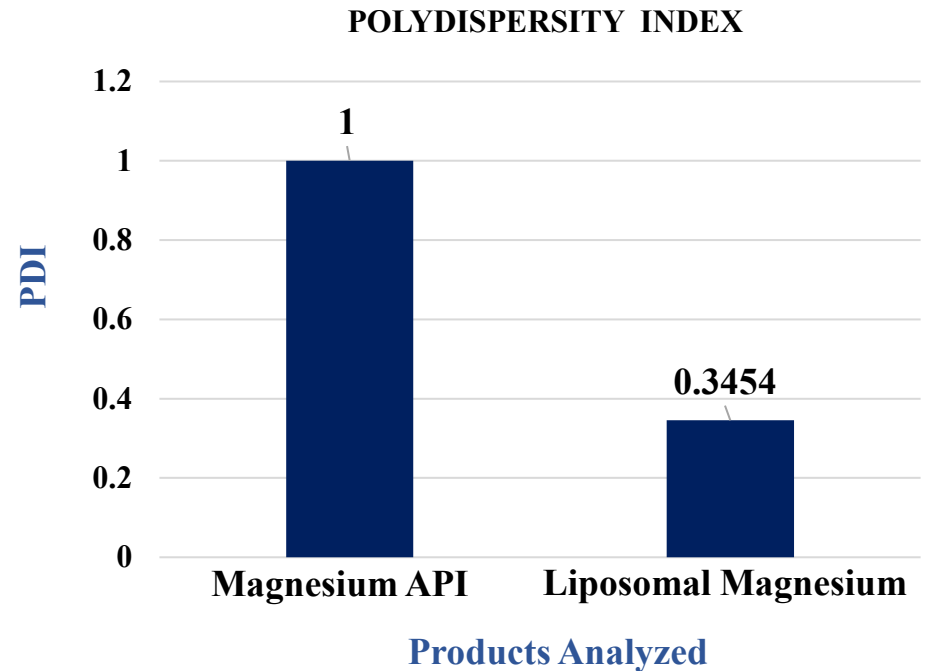


Figure 2 – Chart comparing the Polydispersity Index of Magnesium API and Liposomal Magnesium in solution

- Nanosized, uniform particles offer greater colloidal stability and improved shelf life.
- Smaller particles (**Particle size: 212.2** and **PDI 0.3454**) support increased mucosal permeability and cellular uptake.
- DLS characterization confirms high formulation control and batch-to-batch reproducibility.

Acceptance criteria:

- Particle Size : **< 200 nm**
- Polydispersity Index : **< 1**

3a. Behavior of Liposomal Magnesium

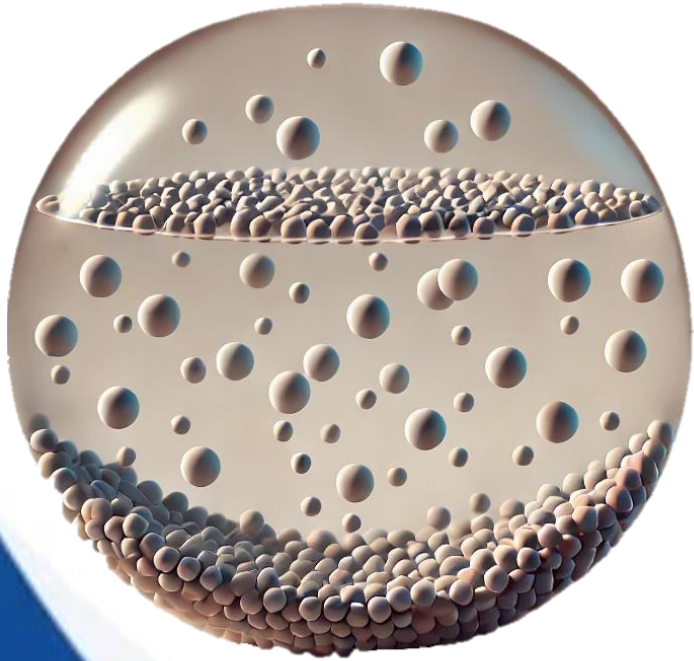


Figure 1 – Illustration of zeta potential, showing the electrostatic interactions of particles in suspension

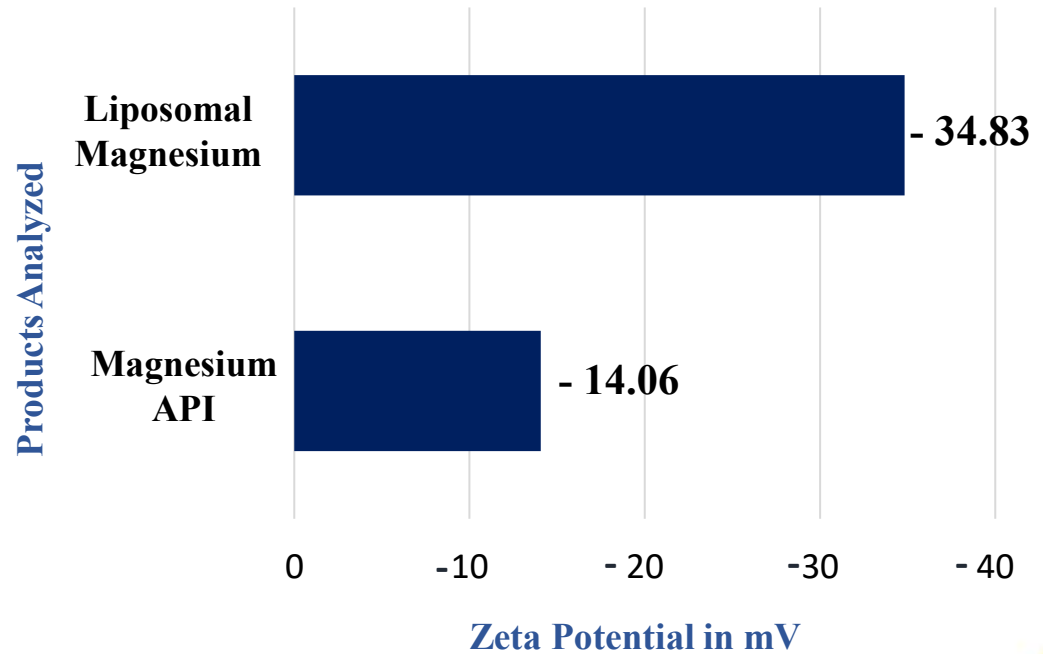


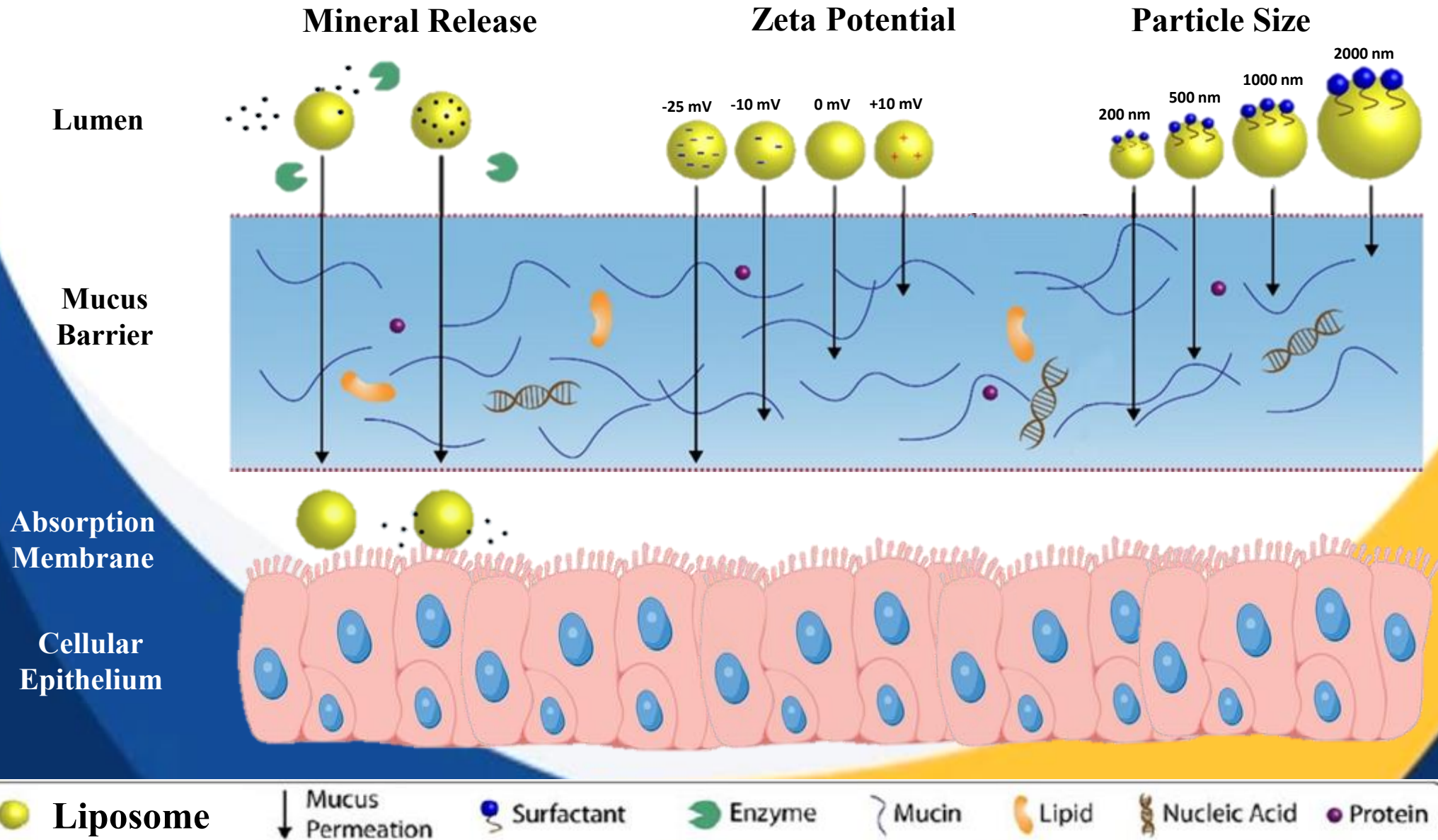
Figure 2 – Chart comparing the zeta potential of Magnesium API and Liposomal Magnesium showing Magnesium in Liposomal form is stable and unlikely to agglomerate in solution.

- Liposomal Magnesium shows **high zeta potential (-34.83 mV)** → excellent colloidal stability.
- Prevents particle aggregation → ensures **uniform suspension**.
- Enhances product shelf life and bioavailability in liquid form.

Acceptance criteria:

- **Zeta Potential : <-30 mV**

3b. Absorption of Liposomal Magnesium Represented Schematically on a Cellular Cross-Section





4b. Summary of FTIR Analysis of Liposomal Magnesium

- 1. Confirmation of the C=O and O-H Groups:** The broad O-H stretching peak at $\sim 3391 \text{ cm}^{-1}$ confirms the presence of hydroxyl groups, while the C=O stretching peak at $\sim 1695 \text{ cm}^{-1}$ confirms the presence of a carbonyl group.
- 2. Hydrophobic Interactions** - C-H stretching at 2918 cm^{-1} and 2845 cm^{-1} and C-H bending at 1450 cm^{-1} , suggesting water and polar group interactions.
- 1. Hydrophilic Interactions** - O-H stretching around 3410 cm^{-1} suggesting water and polar group interactions.
- 2. Encapsulation Stability** - C-H Stretching at 2918 cm^{-1} and 2845 cm^{-1} indicates the presence of lipid alkyl chains, confirming the hydrophobic part of the Liposome structure.

5. Elemental Analysis of Liposomal Magnesium

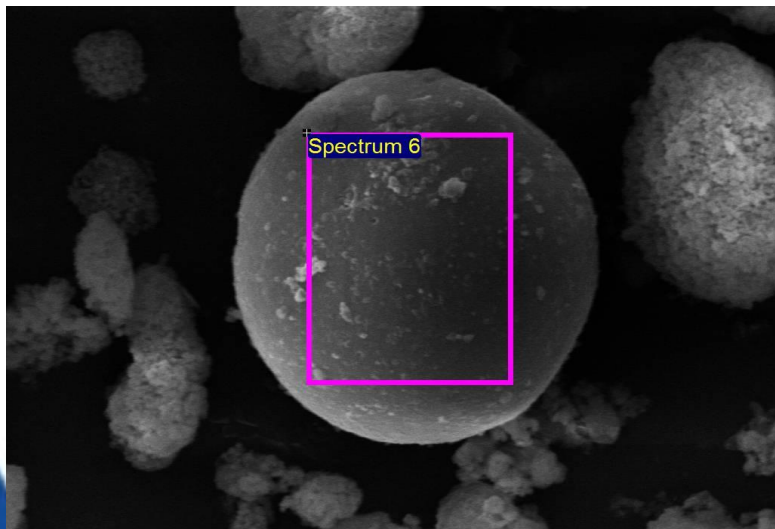


Figure 1 – SEM image of Liposomal Magnesium showing the area scanned using Energy Dispersive X-Ray Spectroscopy (EDAX)

- Magnesium API contains 53.72% magnesium and 46.28% oxygen.
- Liposomal magnesium shows 56.58% carbon, 25.85% oxygen, 17.33% nitrogen, and 0.24% phosphorus.
- The absence of magnesium on the surface suggests it is encapsulated or localized within the liposome.

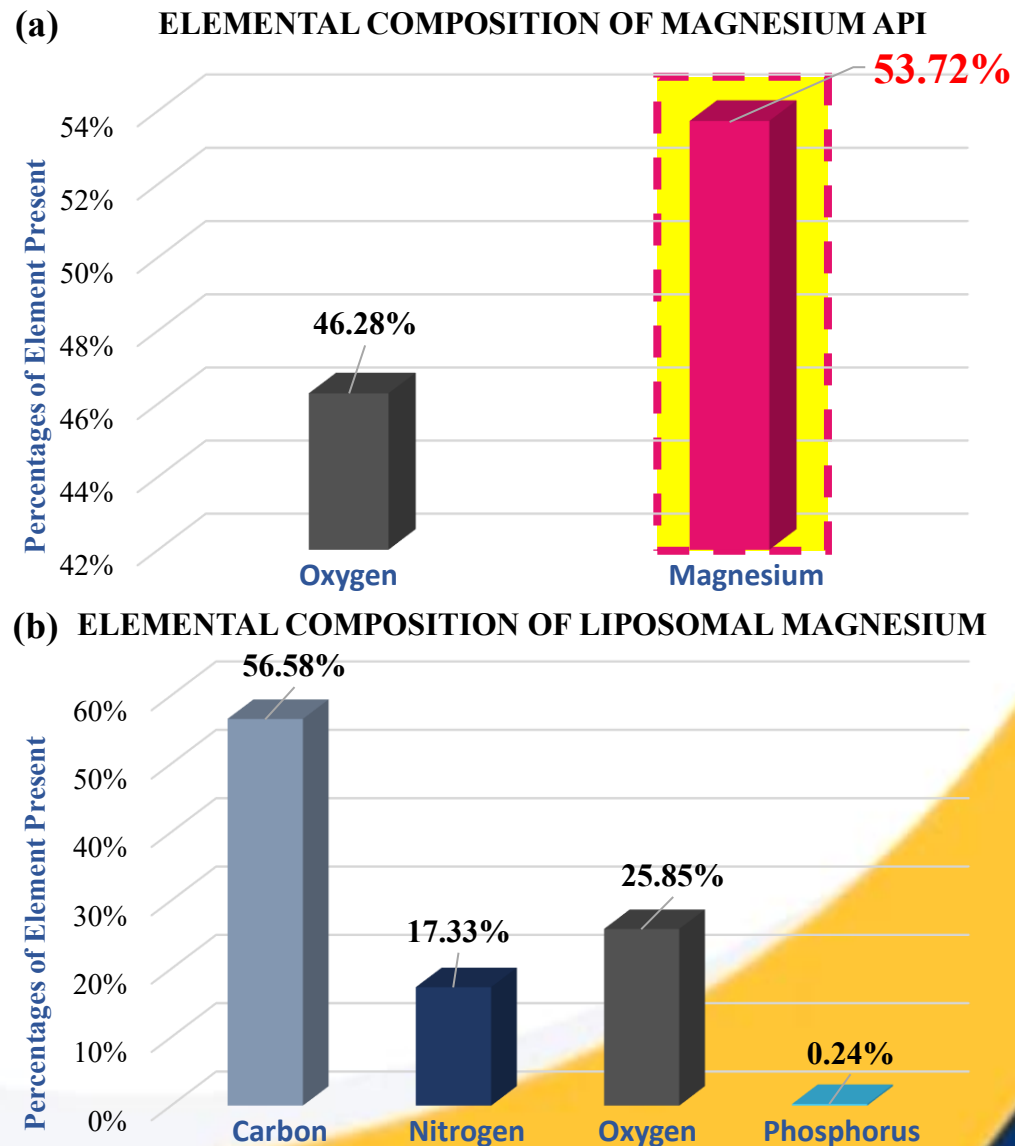


Figure 2 – A graphical representation of the percentages of elements composing (a) Magnesium API and (b) Liposomal Magnesium

6. Morphology of Liposomal Magnesium As Viewed Under a Scanning Electron Microscope

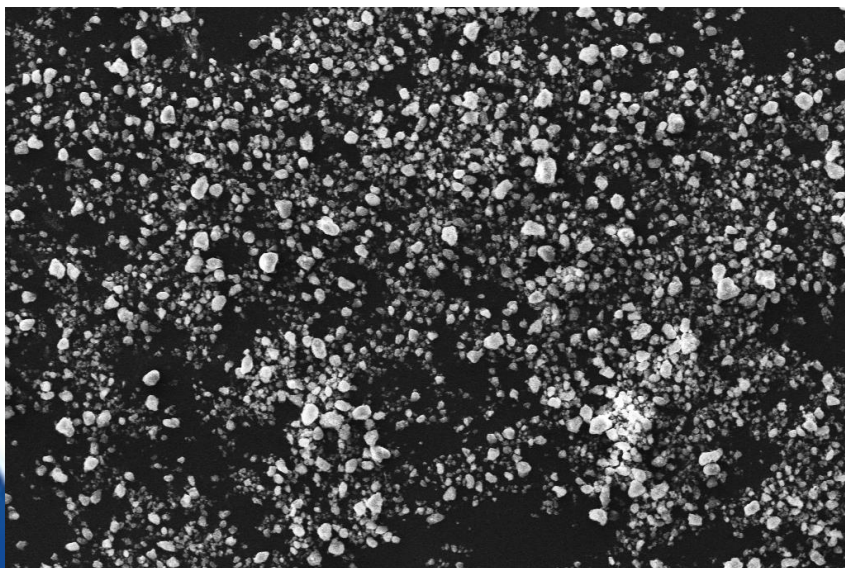
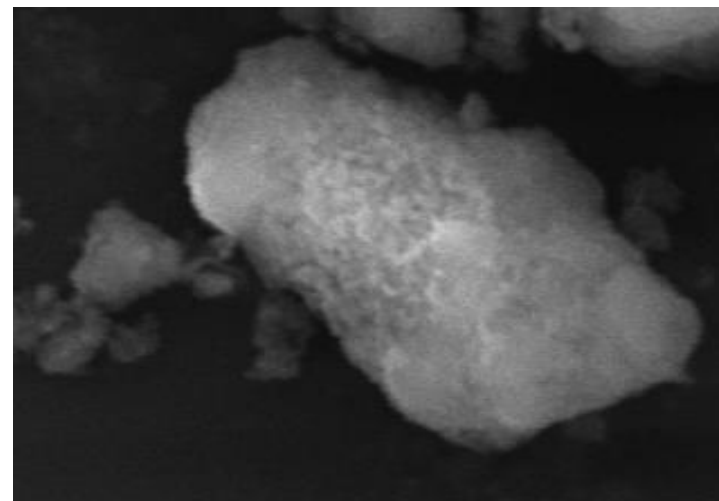


Figure 1 – SEM image of few Magnesium Liposomes scattered within the field of view under observation

- Spherical morphology observed in liposomal Magnesium particles.
- Uniform size distribution seen across the field (Figure 1).
- Particles appear smooth-surfaced at low magnification.
- Spherical and uniform morphology enhances **stability, encapsulation efficiency, and cellular uptake**, making it ideal for liposomal drug delivery.

(a)



(b)

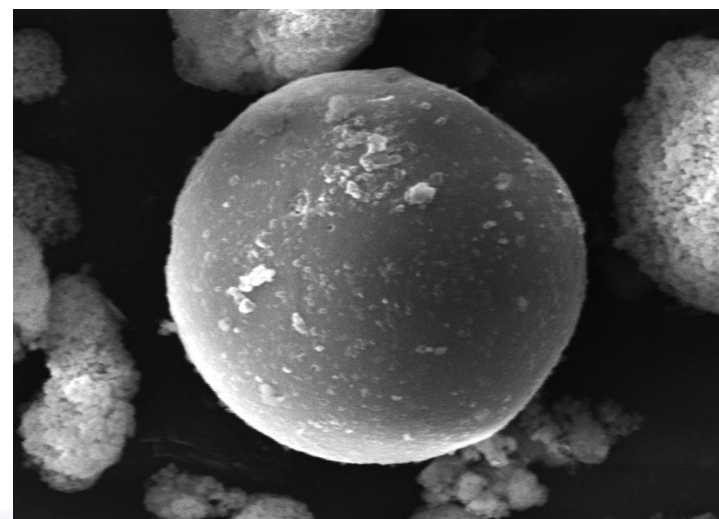


Figure 2 – SEM panels showing transformation from (a) Magnesium API to (b) Liposomal Magnesium after encapsulation.

7. Leakage of Magnesium from Liposomes



Figure 1 – An image representing the storage of formulations in shelves

- **Encapsulation efficiency remains high (80-81%)** throughout 6 months of storage, indicating stable liposome structure.
- **Assay values for free Magnesium remain low (~22%)**, showing minimal leakage over time.
- The formulation shows **excellent retention of Magnesium**, confirming its suitability for long-term shelf storage.

MINERAL LEAKAGE ASSAY

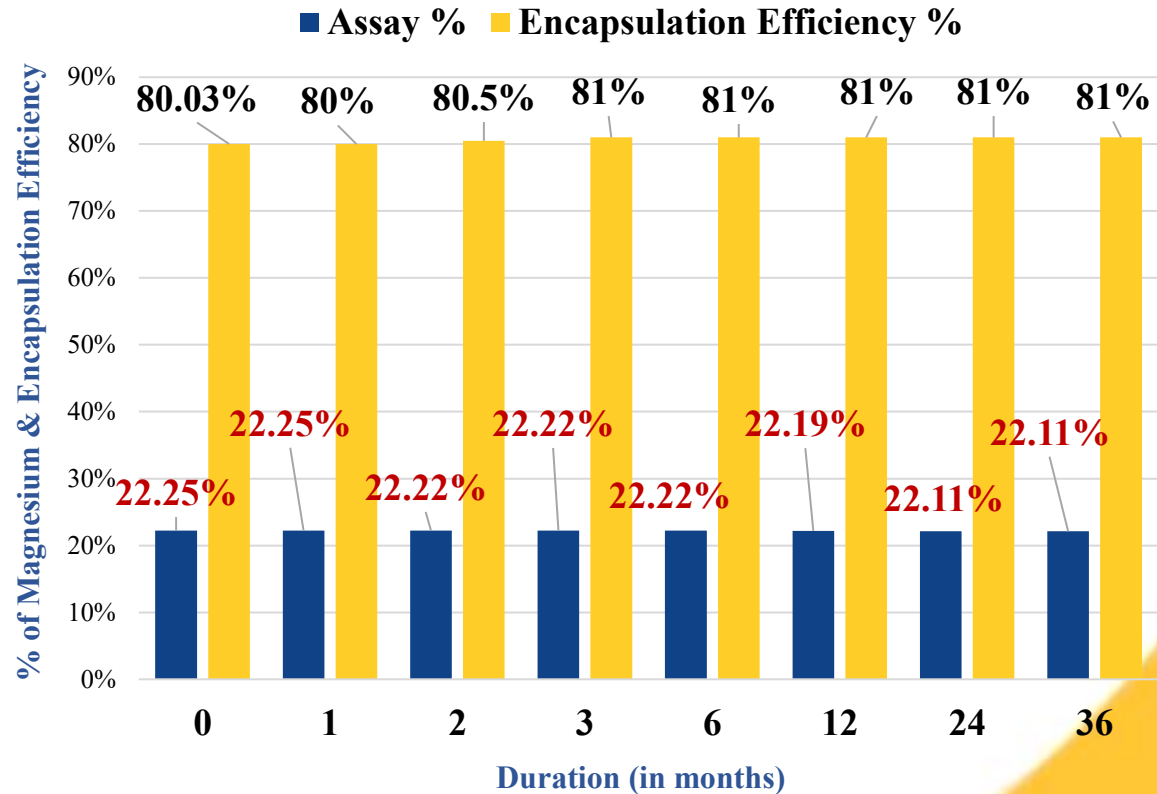


Figure 2 – Chart comparing the stability of Liposomal Magnesium stored over a period of 6 months at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and a relative humidity of $75\% \pm 5\%$.

8. Stability of Magnesium Liposomes at Elevated Temperatures



Figure 1 – An image representing the transport of formulations at elevated temperature.

- Encapsulation efficiency remains high ($\approx 80\%$) even after exposure to 105°C for 4 hours.
- Assay values (approximately 22% at RT and at 105°C) show minimal variation, indicating negligible Magnesium leakage.
- Demonstrates **thermal robustness**, making the formulation suitable for transport and storage in hot climates.

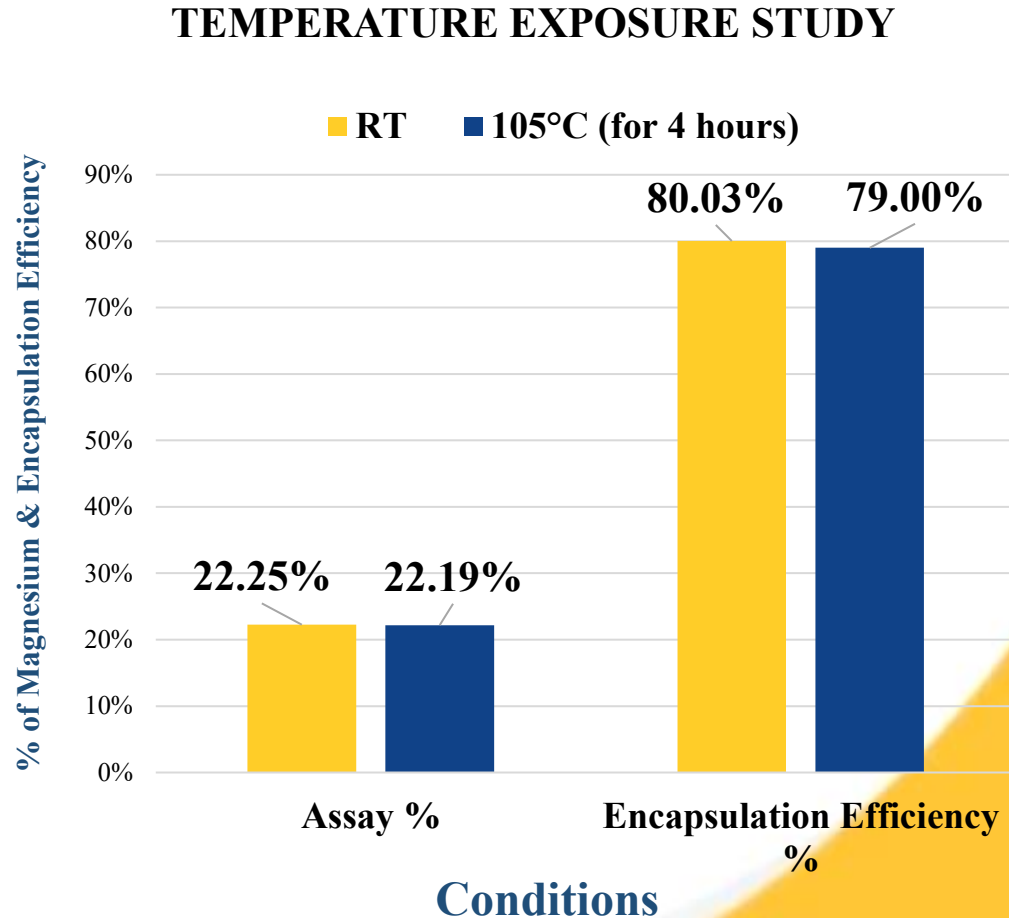
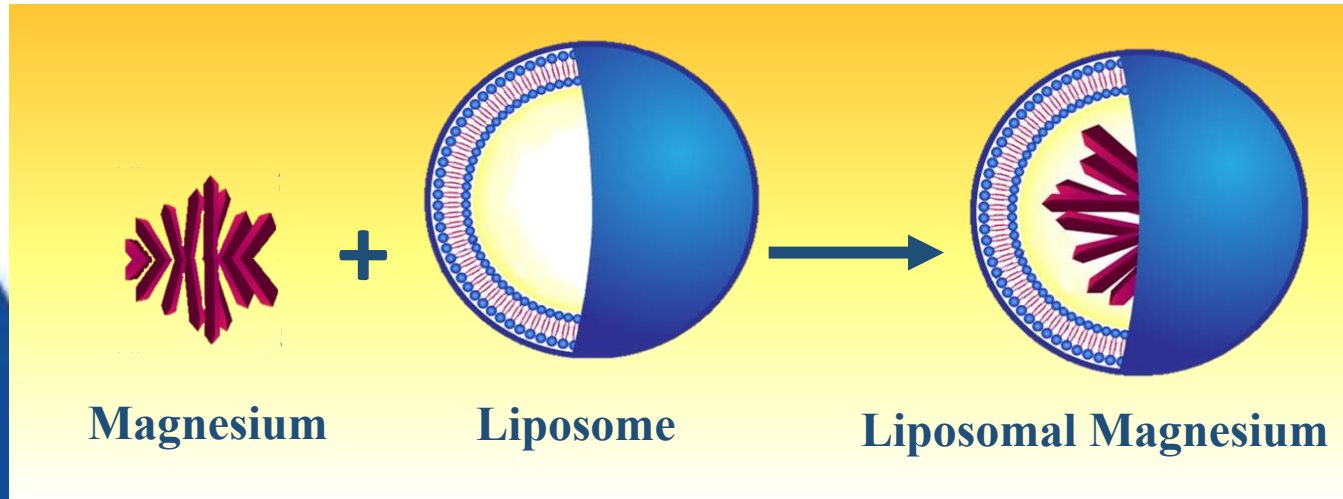


Figure 2 – Chart comparing the stability of Liposomal Magnesium both at room temperature (RT) and at 105°C for 4 hours of exposure.

9. Mineral Loading Capacity



Formulation of Magnesium in Liposomes

- Magnesium loading capacity in Liposomes refers to the amount of Magnesium encapsulated within the Liposome relative to the total weight of the Liposomal formulation.
- A higher Magnesium loading capacity in Liposome ensures more efficient mineral delivery, reduces the amount of Liposome required, and improves therapeutic outcomes.

$$\text{Magnesium loading capacity} = \frac{\text{Mass of Magnesium in Liposomal Magnesium}}{\text{Total mass of Magnesium and Liposome}}$$

Thank You !

WEST BENGAL CHEMICAL INDUSTRIES LIMITED

(A Joint Venture with Government of West Bengal | A cGMP & ISO 9001 : 2015 Certified Company)

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