

ANALYTICAL REPORT

Product name	Magnesium Gluconate USP		Date of issue	26/09/2022		
Batch Size	225.00 Kg		Batch No.	Mg/GL/020922		
Date of Manufacture	September 2022		Date of Expiration	August 2027		
Sr. No.	USP Monograph Analysis	Specification		Observation		
1.	Description	Colourless crystals or white powder or granules, odourless and tasteless.		white powder, odourless and tasteless.		
2.	Solubility	Freely soluble in water; very slightly soluble in alcohol; insoluble in ether.		Freely soluble in water; very slightly soluble in alcohol; insoluble in ether.		
3.	Identification	A (ref.191) B (ref.621)	As per USP	Complies		
4.	Water determination (ref.921)	3.0% to 12.0%		5.58 %		
5.	Assay (on anhydrous basis)	98.0 % - 102.0%		99.74 %		
6.	Heavy metals (ref.231)	NMT 20 ppm		< 20 ppm		
7.	Chloride (ref.221)	NMT 0.05%		< 0.05 %		
8.	Sulfate (ref.221)	NMT 0.05%		< 0.05 %		
9.	pH (5% w/v solution) (ref. 791)	6.0 to 7.8		7.38		
10.	Reducing substances	NMT 1.0%		0.29 %		
Remark: Complies with the USP standard.						
Storage Condition: Preserve in well-closed containers.						

Prepared by	Checked by	Approved by
Chemist - Quality Control Sign: <u>TBhager</u> Date: 26/09/22	H.O.D – Quality Control Sign: <u>D.R.Patel</u> Date: 26/09/22	H.O.D.- Quality Assurance Sign: <u>NDH</u> Date: 26/09/22