

Analysis Report No.: RM/25/010

Document Control No.: QC/SOP/MG/01

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Product Details

Material Name: Magnesium Stearate

Material Code: RM-MG-003

Supplier Name: Thermo-Fisher Scientific

Supplier Batch/Lot No.: MG20211224

GRN Number: GRN-MG-2501

Date of Receipt: 11-Feb-2025

Sampling Date: 12-Feb-2025

Sampled By: Ms. R. Banerjee (QA Executive)

Containers Sampled: CN-MGS-041

Retain Sample Reference: RS-MG-2025-01

Test Specifications and Results

TEST PARAMETER	SPECIFICATION	RESULT	METHOD
Appearance	Fine, white, odorless powder	White, odorless powder	Visual Inspection
Identification (IR)	Conforms to reference spectrum	Conforms	USP <197>
Melting Range	130°C - 140°C	134.5°C - 137.2°C	USP <741>
Assay (Mg Content, Dry Basis)	4.0% - 5.0%	4.4%	Complexometric Titration
Loss on Drying	Not More Than 6.0%	2.9%	USP <731>
Heavy Metals	Not More Than 10 ppm	< 10 ppm	USP <231>
Bulk Density	0.15 - 0.30 g/mL	0.21 g/mL	In-house SOP
Microbial Limits	Total Aerobic Count <= 1000 CFU/g	Within Limits	USP <61>, <62>
	Total Yeast & Mold <= 100 CFU/g	Within Limits	USP <61>, <62>

Certificate of Analysis

Conclusion

All tested parameters conform to the established specifications.

QC Status: COMPLIES

Disposition: The material is APPROVED and RELEASED for transfer to the Raw Material Store.

Authorization

Action	Name & Title	Signature	Date
Analysis Performed By:	Ms. A. Verma (QC Analyst)	A. Verma	12-Feb-2025
Data Reviewed By:	Mr. N. Kaul (QC Supervisor)	N. Kaul	12-Feb-2025
Approved & Released By:	Dr. A. Mehra (QC Manager)	A. Mehra	12-Feb-2025

