

Certificate of Analysis

Analysis Report No.: RM/25/007

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

Document Creation Date: 04-Feb-2025

Product Details

Material Name: (Hydroxypropyl)methyl cellulose (HPMC)

Material Code: RM-HPMC-004

Supplier Name: Sigma-Aldrich

Supplier Batch/Lot No.: HPMC20241218

GRN Number: GRN-HPMC-2506

Date of Receipt: 04-Feb-2025

Sampling Date: 06-Feb-2025

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

Containers Sampled: CN-HPMC-055, CN-HPMC-056

Retain Sample Reference: RS-HPMC-2025-06

Test Specifications and Results

TEST PARAMETER	SPECIFICATION	RESULT	METHOD
Appearance	White to light-colored powder	White to egg-white powder	Visual Inspection
Solubility	Swells in hot water, insoluble in cold water	Swells in hot water	Internal Method
Identification (FTIR)	Conforms to standard spectrum	Conforms	USP <197>
Loss on Drying	Not More Than 5.0%	2.8%	USP <731>
pH (1% solution)	5.0 - 8.0	6.1	USP <791>
Viscosity (2% solution, 20°C)	100 - 150 mPa·s	135 mPa·s	USP <912> / In-house
Heavy Metals	Not More Than 10 ppm	< 10 ppm	USP <231>
Residue on Ignition	Not More Than 1.5%	0.3%	USP <281>
Microbial Limits	Total count NMT 1000 CFU/g	Within Limits	USP <61>, <62>

Certificate of Analysis

Conclusion

All tested parameters conformed 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. P. Sharma (QC Analyst)	P. Sharma	06-Feb-2025
Data Reviewed By:	Ms. Devika Chauhan (QC Supervisor)	D. Chauhan	06-Feb-2025
Approved & Released By:	Dr. M. Santosh (QC Manager)	M. Santosh	06-Jun-2025

