

Kuehne + Nagel (AG & Co.) KG
Betriebsstätte Schkeuditz
Paul-Thiersch-Straße 5-7
D-04435 SCHKEUDITZ

Certificate of Analysis

Date: 26 Sep 2023
Our ref. no.: 43068461 10
Your ref.: LDO-172897

Material:	34538	METHOCEL(TM) E5 Premium LV
Customer material no.:	ID34538P	Hydroxypropyl Methylcellulose
Batch No.:	2444420354	Retest date: 19 May 2028
Quantity:	131 DR	Production date: 21 May 2023

Test	Result	Specification	Unit	Reference
Apparent Viscosity 1)	5.3	4.0 - 6.0	mPa sec	USP/EP/JP/ChP
Loss on drying	1.4	≤ 5.0	%	USP/EP/JP/ChP
Residue on ignition	0.5	≤ 1.5	%	USP/JP/ChP
Sulphated ash	0.5	≤ 1.5	%	CURRENT USP/EP/JP
pH 2)	6.9	5.0 - 8.0		USP/EP/JP/ChP
Methoxyl content	28.8	28.0 - 30.0	%	USP/EP/JP/ChP
Hydroxypropoxyl content	8.5	7.0 - 12.0	%	USP/EP/JP/ChP
Opalescence	Passes test	Passes test		CURRENT EP
Colour Evaluation 3)	Passes test	Passes test		CURRENT EP

Comments

The material property data reported in this COA are representative values obtained in laboratory tests conducted on a product sample taken from the batch produced. The undersigned certifies, that at the time of issuance of this COA, that the material property data reported are the results of the tests conducted. It is the recipient's sole responsibility to determine the suitability and legality of its proposed use of the Products.

If provided in any language other than English, the original English version will control, and the undersigned hereby disclaims responsibility for any errors caused by translation.

It is hereby certified that the material indicated above has been manufactured in accordance with excipient and food additive GMPs, was inspected and tested in accordance with current USP/Ph.Eur./JP/ChP/E464/JECFA/FCC for Hypromellose/Hydroxypropyl Methylcellulose and, unless agreed otherwise, conforms in all respects to the specification relevant thereto.

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Customer material no.: ID34538P
Batch No.: 2444420354
Quantity: 131 DR

METHOCEL(TM) E5 Premium LV
Hydroxypropyl Methylcellulose
Retest date: 19 May 2028
Production date: 21 May 2023

This batch, based on audit testing and process control, is certified to be NMT 10 mg/kg heavy metals (as Pb) and also meets all specification requirements for harmonized identification tests, residual solvents and microbiological limits.

- 1) Measurement conditions: 2% in water @ 20degC
- 2) Measurement conditions: 2% in water
- 3) Measurement conditions: Solution Color

This certificate is generated automatically



Tam D. Nguyen

Quality Control Department