Product Data Sheet

Product Name: METHOCEL K15M PREMIUM HPMC

The following specifications apply to sealed, unopened containers stored under the recommended conditions for the duration of the shelf life.

MATERIAL DATA, PHS

MATERIAL NUMBER	12700427
MATERIAL DESCRIPTION	MCK15M PRM DF25KG 12/P GSS
SPECIFICATION NAME	METHOCEL(TM) K15M Premium Hydroxypropyl Methylcellulose
SPECIFICATION TYPE	SALES SPECIFICATION
SPECIFICATION EFFECTIVE DATE	July 12, 2022
SPECIFICATION SUPERSEDES DATE	April 17, 2020

GOVERNMENT AND INDUSTRY STANDARDS:

Current E464 - European Parliament and Council Directive

Current EP - European Pharmacopoeia

Current JP - Japanese Pharmacopoeia

Current USP - United States Pharmacopeia

U.S. FDA 21 CFR 172.874

U.S. FDA GRAS Notification GRN 000213

VISUAL PROPERTIES, PHS

OPALESCENCE	PASS
	CURRENT EP OPALESCENCE
COLOR EVALUATION	PASS
	CURRENT EP SOLUTION COLOR

PHYSICAL PROPERTIES, PHS

PH (2%)	5.0 - 8.0
	CURRENT USP/EP/JP

EVALUATIONS, PHS

IDENTIFICATION [AB]	PASS
	CURRENT USP/EP/JP

Document ID 2820226
Profile 6091

Product Data Sheet

Product Name: METHOCEL K15M PREMIUM HPMC

EVALUATIONS, PHS

RESIDUAL SOLVENTS [AB]	PASS *CURRENT USP/EP/JP*
SULFATED ASH	<= 1.5 % *CURRENT USP/EP/JP*
MOISTURE (LOSS ON DRYING)	<= 5.0 % *CURRENT USP/EP/JP*
RESIDUE ON IGNITION (%)	<= 1.5 % *CURRENT USP/JP*

VISCOSITY, PHS

APPARENT VISCOSITY	13,275 - 24,780 mPa.s *CURRENT USP/EP/JP BROOKFIELD, 2% IN WATER @ 20DEGC*
APPARENT VISCOSITY (TARGET)	17,700 mPa.s

MICROBIAL, PHS

E.COLI ABSENT PER G [AB]	PASS *CURRENT USP NEGATIVE*
PSEUDO. AERUG. ABS IN 1G [AB]	PASS *CURRENT USP NEGATIVE*
SALMONELLA ABS PER 10G [AB]	PASS *CURRENT USP NEGATIVE*
STAPH. AUR. ABS IN 1G [AB]	PASS *CURRENT USP NEGATIVE*
YEASTS AND MOLDS PER G [AB]	<= 100 /g *CURRENT USP TOTAL COUNT*
TOTAL PLATE COUNT PER G [AB]	<= 100 /g *CURRENT USP TOTAL AEROBIC*

COMPOSITION, PHS

HYDROXYPROPOXYL CONTENT	7.0 - 12.0 % *CURRENT USP/EP/JP*
METHOXYL CONTENT	19.0 - 24.0 % *CURRENT USP/EP/JP*

Product Data Sheet

METALS, PHS

HEAVY METALS (AS PB) [AB] <= 20 mg/kg

CURRENT USP/EP/JP

In the monograph revision provided in PhEur 5.7, the Viscosity method for products with normal viscosities of greater than or equal to 600 mPa.s changed from a rotational viscosity measurement using a constant shear rate to a rotational viscosity measurement using a specified spindle/speed combination. While both methods provide results in units of mPa.s, the resulting viscosities for the two measurements differ due to the non-Newtonian nature of the product. Similarly, in the monograph revision provided in JP 15 and USP 33, the method for viscosity for these same products changed from a solution viscosity measurement to a rotational viscosity measurement using a specified spindle/speed combination. As a result of this change, the unit of measure changed from cPs to mPa.s and the final viscosities for the two measurements also differ due to the non-Newtonian nature of the product. The limits for the USP/EP/JP test item have been selected to ensure equivalency in product viscosities with historical batches which were tested using the previous monograph methods.

Identification Tests A-E specified in the USP and EP monographs are identical to tests 1-5 specified in the JP monograph.

Based on knowledge of the manufacturing process and controlled handling and storage, this product complies with ICH Q3C Residual Solvents Guidance requirements. The solvents listed as Class 1, 2 and by the USP/NF are not used in the manufacturing process.

Tests tagged or noted as "Audit Basis" [AB] are conducted on a frequency that is established for each test.

Audit testing is justified by knowledge of the manufacturing process, process control, use of dedicated equipment and raw material specifications.

For tests conducted on an audit basis, individual batch test results are not provided on the Certificate of Analysis (COA). Instead, a statement of typical properties is given.

Specification limits apply to the material as packaged in the original containers. They do not apply if the material has been repackaged, improperly stored, or if the package has been opened in an uncontrolled environment.

Samples returned for analysis must have been obtained under conditions which prohibit the introduction of microbial contamination. Sterile containers and sampling equipment must be used.

This product meets all requirements of substitution type 2208 in the current USP, EP and JP monographs for Hypromellose.

Product Data Sheet

METALS, PHS

This product is certified Kosher for Passover and Pareve.

This product meets the specific purity criteria for the food additive Hydroxypropyl Methyl Cellulose (E 464) listed within the Official Journal of the European Union.

This product is certified to contain not more than 0.1% of each of the following components: Propylene glycol, Dipropylene glycol, Tripropylene glycol, Dipropylene glycol monomethyl ether and Tripropylene glycol monomethyl ether.

This is a computer generated document and is therefore not signed.