Product Data Sheet

Product Name: METHOCEL E15 PREMIUM LV 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	22947
MATERIAL DESCRIPTION	MCE15 PRM LV BG50LB 40/P
SPECIFICATION NAME	METHOCEL(TM) E15 Premium LV Hydroxypropyl Methylcellulose
SPECIFICATION TYPE	SALES SPECIFICATION
SPECIFICATION EFFECTIVE DATE	July 12, 2022
SPECIFICATION SUPERSEDES DATE	July 24, 2019

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

Current ChP – Chinese Pharmacopoeia

VISUAL PROPERTIES, PHS

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

PHYSICAL PROPERTIES, PHS

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

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EVALUATIONS, PHS

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

VISCOSITY, PHS

APPARENT VISCOSITY	12.0 - 18.0 mPa.s *USP/EP/JP/CHP 2% IN WATER, @ 20DEGC*
APPARENT VISCOSITY (TARGET)	15.0 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 % *USP/EP/JP/CHP*
METHOXYL CONTENT	28.0 - 30.0 % *USP/EP/JP/CHP*

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METALS, PHS

HEAVY METALS (AS PB) [AB]	<= 10 mg/kg	
	USP/EP/JP/CHP	

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.

In compliance with the most current versions of the specified monographs and the corresponding test methods.

This product meets all requirements of substitution type 2910 in the current USP, EP, JP and ChP monographs for Hypromellose.

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 Kosher for Passover and Pareve.

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.

Product Data Sheet

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Document ID 2815782
Profile 6084