THE DOW CHEMICAL COMPANY
SALES SPECIFICATION

Date Printed: 2015-12-04

Effective Date: 2013-03-18
Supersedes Date: 2011-07-27

Name: METHOCEL™ F4M Premium Hydroxypropyl Methylcellulose

Specification Number: 000000053939
Previous Specified Material: 00053939

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

Final Testing Requirements

Test and Test Condition	Limit	Unit	Method	Note
Apparent Viscosity, BROOKFIELD, 2% IN WATER, @ 20DEGC	2663 — 4970 3550 Aim	mPa.s	Current USP/EP/JP	1
Loss on Drying	5.0 Max	%	Current USP/EP/JP	
Residue on Ignition	1.5 Max	%	Current USP/JP	
Ash, Sulfated	1.5 Max	%	Current EP	
pH, 2% in Water	5.0 — 8.0		Current USP/EP/JP	
Assay, Methoxyl	27.0 — 30.0	%	Current USP/EP/JP	
Assay, Hydroxypropoxyl	4.0 — 7.5	%	Current USP/EP/JP	
Appearance, Opalescence	Pass		Current EP	
Appearance, Solution Color	Pass		Current EP	
Identification Tests	Pass		Current USP/EP/JP	2

Test Frequency: audit basis

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Test and Test Condition	Limit	Unit	Method	Note
Heavy Metals, (as Pb)	20 Max	ppm	Current USP/EP/JP	
Test Frequency: audit basis				
Residual Solvents	Pass		Current USP	3
Test Frequency: audit basis				
Microbial Count, Total Aerobic	100 Max	cnt/g	Current USP	4
Test Frequency: audit basis				
Combined Mold & Yeast, Total Count	100 Max	cnt/g	Current USP	5
Test Frequency: audit basis				
Staphylococcus Aureus, negative	Pass		Current USP	6
Test Frequency: audit basis				
Pseudomonas Aeruginosa, negative	Pass		Current USP	7
Test Frequency: audit basis				
Salmonella Species, negative	Pass		Current USP	8
Test Frequency: audit basis				
Escherichia Coli, negative	Pass		Current USP	9
Test Frequency: audit basis				

Final Testing Requirements Notes:

1 In the monograph revision provided in PhEur 5.7, the Viscosity method for products with nominal viscosities of greater than or equal to 600 mPa.s changed from a rotational viscosity measurement at 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 revisions provided in USP 30 & JP 15, 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.

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Final Testing Requirements Notes:

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 test methods.

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

3 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 3 by the USP/NF are not used in the manufacturing process nor is there any potential for them to be present in this product.

4 Microbiological

5 Microbiological

6 Microbiological

7 Microbiological

8 Microbiological

9 Microbiological

General Notes

1 Tests tagged or noted as "Audit Basis" 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.

2 Tests tagged or noted as "Microbiological" 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 product as packaged in the original container. 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.

External Notes

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1 This product meets all requirements of substituion type 2906 in the current USP, EP and JP monographs for Hypromellose.
This product also meets the specific purity criteria for the food additive Hydroxypropyl Methyl Cellulose (E 464) listed within the Official Journal of the European Union.

2 This product is certified Kosher for Passover and Pareve.

3 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.

READ PRECAUTIONARY INFORMATION AND MATERIAL SAFETY SHEETS. THIS PRODUCT IS SHIPPED IN COMPLIANCE WITH APPLICABLE LAWS AND REGULATIONS REGARDING CLASSIFICATION, PACKAGING, SHIPPING AND LABELING.