



## Product Data Sheet

Product Name: METHOCEL A4C PREMIUM  
METHYLCELLULOSE

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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	16531
MATERIAL DESCRIPTION	MCA4C PRM BG50LB 30/P
SPECIFICATION NAME	METHOCEL(TM) A4C Premium Methylcellulose
SPECIFICATION TYPE	SALES SPECIFICATION
SPECIFICATION EFFECTIVE DATE	July 8, 2022
SPECIFICATION SUPERSEDES DATE	May 24, 2021

### GOVERNMENT AND INDUSTRY STANDARDS:

Current EP - European Pharmacopoeia

Current E461 - European Parliament and Council Directive

Current JP - Japanese Pharmacopoeia

Current USP - United States Pharmacopoeia

U.S. FDA 21 CFR 182.1480

### **VISUAL PROPERTIES, PHS**

OPAESCENCE	PASS	<i>CURRENT EP OPAESCENCE</i>
COLOR EVALUATION	PASS	<i>CURRENT EP SOLUTION COLOR</i>

### **PHYSICAL PROPERTIES, PHS**

PH (2%)	5.0 - 8.0	<i>CURRENT USP/EP/JP</i>
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### **EVALUATIONS, PHS**

IDENTIFICATION [AB]	PASS	<i>CURRENT USP/EP/JP</i>
RESIDUAL SOLVENTS [AB]	PASS	<i>CURRENT USP/EP/JP</i>

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### EVALUATIONS, PHS

SULFATED ASH	<= 1.5 % <i>CURRENT USP/EP/JP</i>
MOISTURE (LOSS ON DRYING)	<= 5.0 % <i>CURRENT USP/EP/JP</i>
RESIDUE ON IGNITION (%)	<= 1.5 % <i>CURRENT USP/JP</i>

### VISCOSITY, PHS

APPARENT VISCOSITY	320 - 480 mPa.s <i>CURRENT USP/EP/JP 2% IN WATER, @ 20DEGC</i>
APPARENT VISCOSITY (TARGET)	400 mPa.s

### MICROBIAL, PHS

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

### COMPOSITION, PHS

METHOXYL CONTENT	27.5 - 31.5 % <i>CURRENT USP/EP/JP</i>
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### METALS, PHS

HEAVY METALS (AS PB) [AB]	<= 20 mg/kg <i>CURRENT USP/EP/JP</i>
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Identification Tests A-E specified in the USP and EP monographs are identical to tests 1-5 specified in the JP monograph.

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### **METALS, PHS**

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 current USP/EP/JP for methylcellulose.

This product meets the specific purity criteria for the food additive Methyl Cellulose (E 461) listed within the Official Journal of the European Union.

This product is certified Kosher for Passover and Pareve.

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

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