

Technical Data Sheet

Eastman™ Cellulose Acetate (CA 398-10NF/EP)

Applications

- Medical devices
- Pharmaceutical excipients

Product Description

Eastman™ Cellulose Acetate (CA-398-10NF/EP) is a low viscosity solution grade of cellulose acetate. It is the most commonly used coating material as the semi-permeable membrane for osmotic (controlled-release) drug delivery. It is also used for taste-masking and tableting. CA-398-10NF/EP is made under cGMP and meets the requirements of the National Formulary (NF) and European Pharmacopoeia (EP). CA-398-10NF/EP is available in powder form.

Typical Properties

Property	Test Method	Typical Value, Units
General		
Form		Solid (powder)
Color		White
Odor		Odorless
Acetyl Content		39.3-40.3 %
Loss on Drying		5 wt % max.
Solubility in Water		Negligible
Viscosity	ASTM A	8-13 s

Comments

Properties reported here are typical of average lots. Eastman makes no representation that the material in any particular shipment will conform exactly to the values given.

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SALES SPECIFICATION

EASTMAN

Specification No: 13687E-12
Effective Date: 23 March 2018
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PRODUCT NAME
Eastman™ Cellulose Acetate (CA-398-10 NF-EP) (PM 13687-0E)

SPECIFICATIONS		
PROPERTY	LIMITS	TEST METHOD
ASTM-A Viscosity, s	8.0 – 13.0	TECE-A-NF-13687-V-55
*NF Acetyl, %	39.3 – 40.3	TECE-A-NF-13687-POT-47
*NF Loss on Drying, W%	5.0 max	TECE-A-NF-13687-GA-63
*NF Free Acid, W%	0.1 max	TECE-A-NF-13687-POT-47
*NF Infrared Identity	PASS	TECE-A-NF-G-IR-5
NF Residue on Ignition, W%	0.1 max	TECE-A-NF-13687-GA-62
NF Residual Solvents	PASS	TECE-A-NF-13687-GC-50
EP Total Aerobic Microbial Count, 10 ³ CFU/g max	PASS	EP Method
EP Total Yeasts and Molds Count, 10 ² CFU/g max	PASS	EP Method
EP Escherichia coli (absent)	PASS	EP Method
EP Salmonella (absent)	PASS	EP Method

* NOTE: These tests are equivalent to the corresponding EP tests.

ADDITIONAL INFORMATION
This product is in compliance with the requirements in USP General Chapters <232> Elemental Impurities, ICH Q3D Guideline for Elemental Impurities and EP Metal Catalyst or Metal Reagent Residues.

Eastman™ is a trademark of Eastman Chemical Company.

For reasons of safety and accuracy, the person performing this procedure must be thoroughly trained and under the supervision of a professional person who is knowledgeable in the relevant science. Equipment and materials described should be used in accordance with safety precautions recommended by their manufacturers. Limits in this specification are applicable only to data obtained by the referenced test method.

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