

## SALES SPECIFICATIONS

Sales Specification No : 29254-12

Effective Date : 05/07/2018

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### PRODUCT NAME

**Eastman(TM) Cellulose Acetate CA-320S NF/EP**

### SPECIFICATIONS

PROPERTY	LIMITS	TEST METHOD
NF Acetyl, %	30.0 - 33.0	TECE-A-NF-29254-POT-95
NF Loss on Drying, W%	0.0 - 5.0	TECE-A-NF-29254-GA-83
NF Free Acid, W%	0.0 - 0.1	TECE-A-NF-29254-POT-95
NF Infrared Identity	PASS	TECE-A-NF-G-IR-5
NF Residue on Ignition, W%	0.1 MAX	TECE-A-NF-29254-GA-84
NF Residual Solvents	PASS	TECE-A-NF-29254-POT-95
EP TAMC, 10 <sup>3</sup> CFU/g max	PASS	EP METHOD
EP TYMC, 10 <sup>2</sup> CFU/g, max	PASS	EP METHOD
EP Escherichia coli	PASS	EP METHOD
EP Salmonella	PASS	EP METHOD
Pyridine Viscosity, cps	170 - 280	TECE-A-NF-29254-V-60

**ADDITIONAL INFORMATION** This specification describes a special grade of Eastman# Cellulose Acetate (CA-320S NF/EP), which is marketed for use in drugs or delivery devices. The product, described in this specification, is judged to be produced and handled in accordance with current Good Manufacturing Practices (cGMP) and meets each of the requirements according to the methods of testing the product as set forth in the U.S. Pharmacopeia / National Formulary and the European Pharmacopoeia. Eastman# Cellulose Acetate (CA-320S NF/EP) is available as a white pellet that may, on occasion, have some discolored particles present. These discolored particles, ranging from translucent off-white to black, are overheated Eastman# Cellulose Acetate (CA-320S NF/EP) particles or low substituted cellulose acetate occurring in the manufacturing process. These particles, when present, are in parts per million and are not preventable in our manufacturing process. They will either dissolve in the customer#s solvent system (dependent upon the solvent system) or can be removed by filtration of the customer#s solution. 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.

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Sales Specification available on Eastman.com

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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