PRODUCT NAME

Eastman™ Cellulose Acetate CA-320S NF/EP

SPECIFICATIONS

PROPERTY	LIMITS	TEST METHOD
Pyridine Viscosity, cps	170-280	TECE-A-NF-29254-V-60
*NF Acetyl, %	30.0 – 33.0	TECE-A-NF-29254-POT-95
*NF Loss on Drying, W%	5.0 max	TECE-A-NF-29254-GA-83
*NF Free Acid, W%	0.1 max	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 Heavy Metals, NMT 10µg/g	PASS	TECE-A-NF-G-VCC-71
NF Residual Solvents	PASS	TECE-A-NF-29254-POT-95
EP Heavy Metals, ppm (10 max)	PASS	TECE-A-NF-29254-VCC-72
EP Total Aerobic Microbial Count, CFU/g 10^3 max	PASS	EP Method
EP Total Yeasts and Molds Count, CFU/g 10^2 max	PASS	EP Method
EP Escherichia coli (absent)	PASS	EP Method
EP Samonella (absent)	PASS	EP Method
Acetyl Calculated from OH Titration, wt%	N/A	TECE-A-CL-G-POT-41

*These tests are equivalent to the corresponding EP tests

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.

Eastman Chemical Company · P.O. Box 511 · Kingsport, Tennessee 37662 USA · 1-800-EASTMAN · 1-423-229-2000 · www.EASTMAN.com