

PRODUCT SPECIFICATION BULLETIN

Ac-Di-Sol[®] SDW-802 croscarmellose sodium, NF, Ph. Eur., JP, E-468

Compendial Standards	Specifications
Identification	Passes
NaCl and NaGly, %	NMT 0.50
Degree of substitution	0.63 - 0.85
Content of water soluble material, %	1.0 - 10.0
Setting volume, mL	10.0 - 30.0
pH	5.5 - 7.0
Loss on drying, %	NMT 6.0
Heavy metals, %	NMT 0.001
Sulfated ash %	14.0 - 28.0
Arsenic, ppm	NMT 2.0
Microbial limits:	
Total aerobic count, cfu/g	NMT 100
Total fungi (yeast and mold), cfu/g	NMT 20
Escherichia coli	Not detected by test
Additional FMC specifications	
Microbial limits:	
Pseudomonas aeruginosa	Not detected by test
Staphylococcus aureus	Not detected by test
Salmonella species	Not detected by test

This product meets the requirements for Residual Solvents in the United States Pharmacopeia <467> and complies with the ICH Guide Q3C for Residual Solvents.

Storage conditions: Store at ambient conditions. Keep containers sealed; material is very hygroscopic.

Re-evaluation date: Three (3) years from date of manufacture, if storage conditions stated above are observed.

Re-evaluation requirements: FMC recommends that after the above re-evaluation date, the customer perform the loss on drying test.

NMT = Not More Than

NLT = Not Less Than

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