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Specification Sheet

CROSCARMELLOSE SODIUM NF EP

Code No.	SCN No.	CAS No.	Effective Date	Product Manager	Rev. No.	Approved By
CCMAIP	1405	74811-65-7	March 28, 2012	RMK	No. 6	CDS

CHARACTERISTICS:	The sodium salt of a cross-linked, partly <i>O</i> -(carboxymethylated) cellulose. It is a white, odorless, very hygroscopic powder that is slightly soluble in water.
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SPECIFICATIONS:	Identification	
	A, B, C	To pass tests
	Residue on ignition	14.0-28.0%
	Heavy metals	
	EP	20 ppm max
	NF	10 ppm max
	Sodium chloride % + sodium glycolate %	Not more than 0.5%
	Water-soluble material	Not more than 10%
	Degree of substitution (dried basis)	0.60-0.85
	Loss on drying	Not more than 10.0%
	Total Aerobic Microbial Count	Not more than 1000 cfu/g
	Mold and yeast	Not more than 100 cfu/g
	Escherichia coli	Absent
	pH	5.0-7.0
	Settling volume	10.0-30.0 mL
	Residual solvents	Passes
Methanol, Class 2 solvent (insoluble method)	Not more than 3,000 ppm	
Class 3 solvent: Ethanol	Not more than 5,000 ppm	

STOCKING POINTS:	Miami, FL
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PACKAGING:	25 kg drum; 18 drums per pallet = 450 kgs; 20 pallets per 9mt container
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APPLICATIONS:	A disintegration and dissolution agent used in capsules and tablets prepared by direct compression or by wet granulation.
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STORAGE INSTRUCTIONS AND SHELF LIFE:	Recommended retest date of 3 years from date of manufacture; Maximum 5 year shelf life. Store in a temperate dry area away from other incompatible materials.
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OTHER:	Kosher; complies with USP NF EP Monographs.
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