

CROSCARMELOSE SODIUM SPECIFICATIONS AS PER USP/EP/BP/IP/IH

Sr. No.	TESTS	SPECIFICATIONS
1.	Description	White or greyish white, Hygroscopic powder as USP/NF Ph.Eur., BP
2.	Solubility	Practically insoluble in acetone, in anhydrous ethanol and in toluene as USP/NF, Ph. Eur., BP
3.	Identification (A) (BP/EP/USP)	Infrared Spectroscopy: 197A or 197K.
	Identification (A) (IP)	The Croscarmellose Sodium absorbs the methylene blue and settles as a blue fibrous mass.
4.	Identification (B) (BP/EP/USP)	The Croscarmellose Sodium absorbs the methylene blue and settles as a blue fibrous mass.
	Identification (B) (IP)	A reddish-violet colour develops at the interface.
5.	Identification (C) (BP/EP/USP/IP)	Intense yellow colour to a nonluminous flame
	Identification (C) (IP)	The solution prepared from the sulphated ash in the test for Heavy metals gives reaction (a) of sodium salts
6.	Degree of substitution (IP/BP/EP/USP)	0.60 to 0.85
7.	Loss on Drying (IP/BP/EP/USP)	NMT 10.0%
8.	pH (IP/BP/EP/USP)	5.0-7.0
9.	Content of Water - Soluble Substance (IP/BP/EP/USP)	1.0 - 10.0 %
10.	Residue on Ignition / Sulphated Ash (IP/BP/EP/USP)	14.0% to 28.0%
11.	Settling volume (IP/BP/EP/USP)	10 to 30 ml
12.	Sodium chloride & sodium glycolate (IP/BP/EP/USP)	NMT 0.5%
13.	Heavy metals (IP)	NMT 10 PPM
14. Microbial Analysis (IP/BP/EP/USP)		
i	Total Viable Aerobic Count	N.M.T. 1000 cfu/g
ii	Total yeast & mold Count	N.M.T 100 cfu/g
iii	Staphylococcus aureus	Absent
iv	Escherichia Coli.	Absent
v	Pseudomonas aeruginosa	Absent
vi	Salmonella species	Absent