



## CROCARMELLOSE SODIUM

Sr. No.	TESTS	SPECIFICATION			
		IP	USP	BP	
1.	Description	A white or grayish-white powder	White, free-flowing powder	White or grayish-white powder	
2.	Solubility	----	Partially soluble in water; insoluble in Alcohol, in Ether and in other organic Solvent	Practically insoluble in Acetone, in Anhydrous Ethanol and in Toluene	
3.	Assay	6.5% to 10.8%			
4.	Identification	As per IP	As per USP	As per BP	
5.	pH	5.0 to 7.0	5.0 to 7.0	5.0 to 7.0	
6.	Degree of Substitution	As per IP	0.60% to 0.85%	0.60% to 0.85%	
7.	Sodium Chloride and Sodium Glycollate	As per IP	NMT 0.5%	Maximum 0.5%	
8.	Water Soluble Substance	As per IP	NMT 10 ppm	Maximum 10.0%	
9.	Heavy Metals	NMT 20 ppm	NMT 10 ppm	Maximum 20 ppm	
10.	Settling Volume	10.0 ml to 30.0 ml	10.0 ml to 30.0 ml	10.0 ml to 30.0 ml	
11.	Microbial Enumeration Test & Tests for Specified Microorganism	----	As per USP	----	
12.	Sulphated Ash (IP) Residue on Ignition (USP)	14.0% to 28.0%	14.0% to 28.0%	14.0% to 28.0%	
13.	Loss on Drying	NMT 10.0%	NMT 10.0%	Maximum 10.0%	
14.	Particle Size Distribution	----	----	As per BP	
15.	Hausner Ratio	----	----	As per BP	
16.	Microbial Contamination	TAMC	As per IP	----	10 <sup>3</sup> CFU/g
		TYMC			10 <sup>2</sup> CFU/g