

SPECIFICATION

Product Name: Sodium Croscarmellose (Water Soluble) BP Grade
Chemical Formula: C ₈ H ₁₆ O
CAS Number: 74811-65-7
Molecular Weight: 982.44 g/mol
Appearance: White powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min./Max.)
Identification A:	-	Complies	The substance to be examined absorbs the methylene blue and Settles as a blue fibrous mass. A reddish violet color develops at the interface. The solution gives reaction of sodium.
Identification B:	-	Complies	
Identification C:	-	Complies	
pH	-	6.30	5.0 to 7.0
Degree of Substitution	-	0.67	0.60 to 0.85
Water soluble content	%	8.4%	NMT 10.0%
Sodium chloride and Sodium Glycollate	%	0.38%	The sum of the percentages of sodium chloride and sodium glycolate should NMT 0.5%
Settling volume	ml	16ml	10 ml to 30 ml
Sulfated ash	%	18.6%	14% to 28%
Loss on drying	%	5.2%	NMT 10.0%
Microbial Limit Test			
Aerobic counts	cfu/g	110cfu/g	NMT 1000 cfu/g

Yeast & Mould count	cfu/g	25cfu/g	NMT 100 cfu/g
E.coli	-	Absent	Absent
Heavy Metal (INH)	PPM	< 10 PPM	NMT 10 PPM

Physical Properties

- Solubility: Insoluble in water. Insoluble in ethanol. Insoluble in methanol. Insoluble in acetone. Insoluble in ether. Insoluble in chloroform.

Shelf Life & Storage

- Shelf Life: 5 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed container in a cool, dry, and well-ventilated place, protected from moisture, humidity, heat, and contamination.

Applications

- Use: Widely used in superdisintegrant in pharmaceutical and nutraceutical solid dosage forms. It rapidly absorbs water and swells, promoting fast tablet disintegration and improved dissolution of active ingredients.
- Dosage: Depends on Tablet formulation, Compression force, Desired disintegration time, Active pharmaceutical ingredient (API), Manufacturing process (direct compression or wet granulation), Regulatory and pharmacopeial requirements.

Packaging

- Standard Packing: 25 Kg woven pp bag with inner liner or as per customer requirement.
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.
* Specifications are based on the manufacturer's provided specifications.