

Technical Data Sheet – Croscarmellose Sodium

1. Product Identification

- Product Name: Croscarmellose Sodium
- Synonyms: Cross linked Sodium Carboxymethylcellulose
- CAS Number: 74811-65-7
- HS Code: 39123100
- Regulatory Status: USP–NF, Ph. Eur., JP, IP and ChP compliant

2. Product Description

Croscarmellose Sodium is a white to off-white, free-flowing, hygroscopic powder. It functions as a superdisintegrant in oral solid dosage forms, facilitating rapid tablet disintegration through swelling and wicking action.

3. Pharmacopeial Specifications

Parameter	Specification / Range	Method / Reference
Identification	Meets pharmacopeial test	USP-NF / Ph-Eur / JP /ChP / IP
pH (1% dispersion)	5.9 - 7.0	USP-NF / Ph-Eur / JP /ChP / IP
Loss on Drying	NMT 6.0%	USP-NF / Ph-Eur / JP /ChP / IP
Degree of Substitution (DS)	0.63 - 0.85	USP-NF / Ph-Eur / JP /ChP / IP
NaCl and NaGly	NMT 0.50%	USP-NF / Ph-Eur / JP /ChP / IP
Heavy Metals	Max 10 ppm	USP-NF / Ph-Eur / JP /ChP / IP
Microbial Limits	As per pharmacopeia	USP-NF / Ph-Eur / JP /ChP / IP

4. Physical Parameters (Typical Values)

- Appearance – White/off-white, free-flowing powder
- Structure : Fibrous
- Bulk Density (g/mL): ~0.62
- Tapped Density (g/mL): ~0.71
- Carr's Index (%): ~15.5%
- Hausner Ratio: ~1.15
- Particle Size Distribution (PSD): d50 ~ 45 µm
- Moisture Content (%): 4 – 7 (typical)

5. Functional Performance

- Recommended Use Level: 0.5 – 5.0% depending on formulation
- Mode of Action: Rapid swelling and wicking effect to promote tablet breakup

6. Safety and Regulatory

- Pharmacopeial Compliance: USP–NF, Ph. Eur., JP, IP and ChP
- Toxicology: GRAS (Generally Recognised as Safe)

- Inhalation Risk: Low-dust grades available (if applicable)

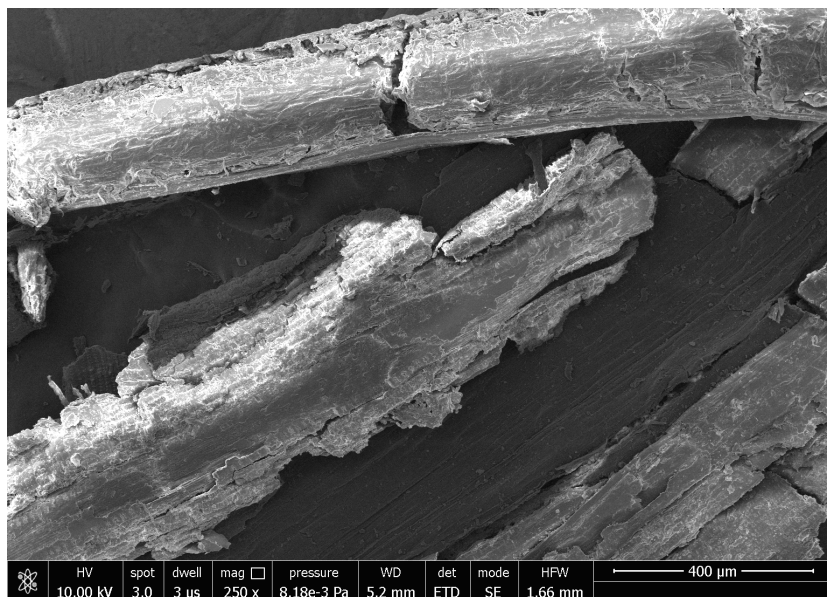
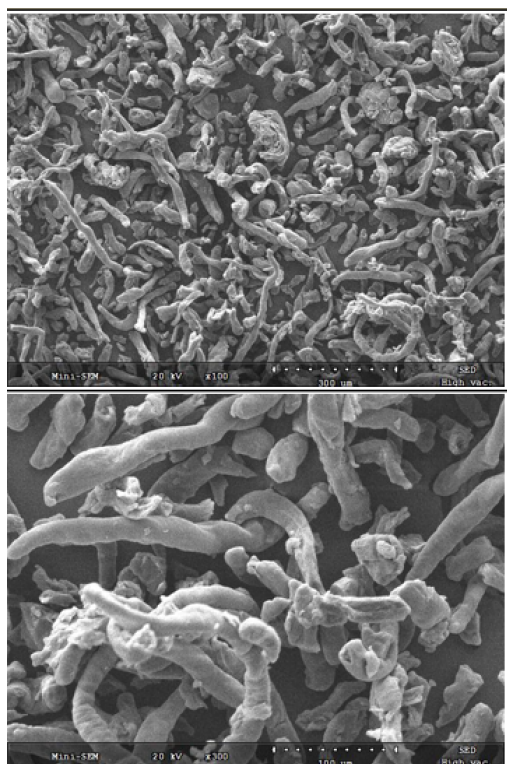
7. Packaging and Storage

- Standard Packaging: 25 kg cartons / HDPE lined bag
- Shelf Life: 5 years when stored in original container
- Storage Conditions: Store in a cool, dry place. Protect from moisture.

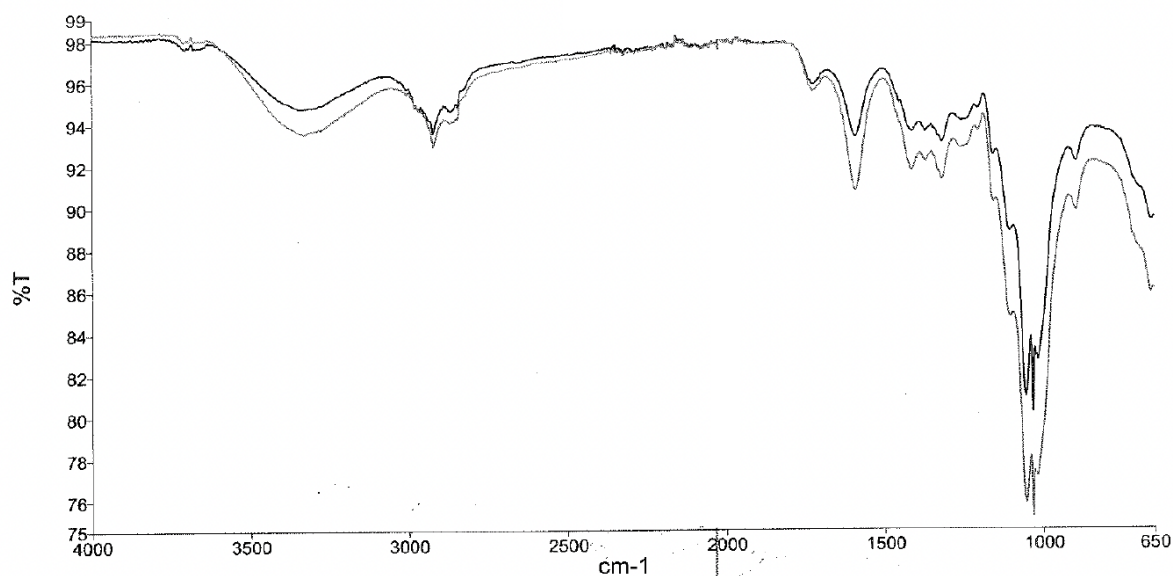
8. Certifications and Additional Information

- Origin: Cotton linter
- Allergen Status: Allergen-free
- BSE/TSE Status: Complies (no animal-derived material)
- GMO Status: Non-GMO
- Halal / Kosher Certification: Available on request

9. SEM Images



10. IR Spectrum



Disclaimer

The information provided in this Technical Data Sheet is intended as a guide for formulators and quality teams. Values listed under 'Typical' are not to be considered as specifications. Final suitability must be confirmed by the end user through formulation trials and regulatory review.