



ALCON BIOSCIENCES PRIVATE LIMITED

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SPECIFICATION OF CROSCARMELLOSE SODIUM.

Product Name: Croscarmellose Sodium

| TEST | SPECIFICATION |
|---|--|
| Appearance | White free flowing powder |
| Solubility | Practically soluble in water, insoluble in alcohol, in ether and in other organic solvents. |
| Identification | Substance absorbs methylene blue and settles as a blue, fibrous mass. A reddish- violet color develops at the interface Sodium Test A dense precipitate is formed Impact an intense yellow color to nonluminous flame. |
| pH | 5.0 to 7.0 |
| Degree of substitutuion | 0.60 to 0.85 |
| Water soluble Content | NMT 10.0% |
| Sodium chloride and Sodium Glycolate | The sum of percentage of Sodium chloride and Sodium Glycolate should NMT 0.5% |
| Heavy Metals | NMT 10ppm |
| Loss on drying | NMT 10.0% |
| Residue on ignition | 14% to 28% |
| Settling volume | 10ml to 30ml |
| Microbial Limit | |
| Aerobic Count | NMT 1000cfu/g |
| Yeast and mould count | NMT 100cfu/g |
| E.Coli | Absent |

REMARK: THE PRODUCT COMPLIES AS PER BP/USP SPECIFICATION