



Maple Biotech Pvt. Ltd.

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| SPECIFICATIONS OF MYLCEL-10 LOW SUBSTITUTED CARBOXYMETHYLCELLULOSE SODIUM SALT | | |
|--|---|--|
| TEST | SPECIFICATIONS | TEST METHOD |
| Appearance | white to yellowish white, finely fibrous odourless powder | |
| Solubility | Practically insoluble in acetone, in anhydrous ethanol and in toluene. It swells in water to form a gel (Ph Eur) | |
| Identification | A: Shake 2 g of Low-Substituted Carboxymethylcellulose Sodium with 100 mL of sodium hydroxide solution (2M): a suspension is produced. | USPNF & Ph Eur |
| pH | 6.0 to 8.5 (USPNF & Ph Eur) | USPNF & Ph Eur |
| Loss on Drying | Max 10% | USPNF & Ph Eur |
| Residue on Ignition (Sulphated Ash) @800° C | 6.8 to 8.9 | USPNF & Ph Eur |
| Assay (% Sodium) | 2.2 to 2.9 | USPNF & Ph Eur |
| Degree of Substitution | 0.17 to 0.23 | |
| Viscosity of 1% solution in 10%NaOH | 150 to 400 m.pas | Viscosity of 1% Mylcel solution in 10%NaOH |
| Sodium Chloride & Glycolate | NMT 0.5% | USPNF & Ph Eur |
| Water Soluble substance | NMT 18% | USPNF & Ph Eur |
| Heavy Metals | Max 20 ppm (USPNF & Ph Eur) | USPNF & Ph Eur |
| Arsenic | Less than 1 ppm (Nymcel) Not included in USPNF & Ph Eur | USPNF & Ph Eur |
| Settling Volume | 15 to 35 ml | USPNF & Ph Eur |
| Total Aerobic Microbial Count | max. 1000 cfu/gm | |
| Total Molds and Yeast Count | Max. 100 cfu/ gm | |
| <i>E. Coli</i> | absent | |
| <i>Salmonella</i> | absent | |
| <i>S. Aureus</i> | absent | |
| <i>Pseudomonas</i> | absent | |



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| Specifications of MYLCEL-16 LOW SUBSTITUTED CARBOXYMETHYLCELLULOSE SODIUM SALT | | |
|---|--|--|
| TEST | SPECIFICATIONS | TEST METHOD |
| Appearance | white to yellowish white, finely fibrous odourless powder | |
| Solubility | Practically insoluble in acetone, in anhydrous ethanol and in toluene. It swells in water to form a gel (Ph Eur) | |
| Identification | A: Shake 1 g of Low-Substituted Carboxymethylcellulose Sodium with 100 mL of sodium hydroxide solution (2M): a suspension is produced. | USPNF & Ph Eur |
| pH | 6.0 to 8.5 (USPNF & Ph Eur) | USPNF & Ph Eur |
| Loss on Drying | Max 10% | USPNF & Ph Eur |
| Residue on Ignition (Sulphated Ash) @800o C | 10.8 to 13.3 | USPNF & Ph Eur |
| Assay (% Sodium) | 3.5 to 4.3 | USPNF & Ph Eur |
| Degree of Substitution | 0.28 to 0.36 | |
| Viscosity of 1% solution in 10%NaOH | 150 to 400 m.pas | Viscosity of 1% Mylcel solution in 10%NaOH |
| Sodium Chloride & Glycolate | NMT 0.5% | USPNF & Ph Eur |
| Water Soluble substance | NMT 70% | USPNF & Ph Eur |
| Heavy Metals | Max 20 ppm (USPNF & Ph Eur) | USPNF & Ph Eur |
| Arsenic | Less than 1 ppm (Nymcel) Not included in USPNF & Ph Eur | USPNF & Ph Eur |
| Settling Volume | 15 to 35 ml | USPNF & Ph Eur |
| Total Aerobic Microbial Count Total Molds and Yeast Count | max. 1000 cfu/gm Max. 100 cfu/ gm | |
| E. Coli Salmonella S. Aureus Pseudomonas | absent absent absent absent | |