

NECROFILL®

NECROFILL® is a Native Maize/Tapioca/Potato Starch provide excipient benefits as a disintegrant and filler or binder, as well as nutrient benefits when used as a carbohydrate source. These benefits are provided to both pharmaceutical and nutraceutical product forms. These include swallowable tablets; hard capsules; and blends, granules, pellets premix.

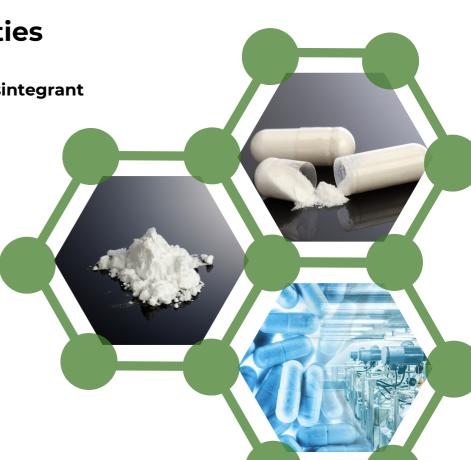
Key attributes: High amylopectin starch, Improve starch paste stability

Applications

- Oral Dosage for Pharmaceutical and/or Nutraceuticals
 - Swallowable tablet
 - Hard capsules
 - Blends, Granules, Pellets Premix

Functional Properties

- Excipient
 - Disintegrant, Super Disintegrant
 - Filler or Filler/Binder
- Nutrients
 - Carbohydrate Source



NECROFILL®

| Native Maize Starch/Tapioca Starch/Potato Starch CAS No. 9005-25-8 | | |
|--|---|-----------------------|
| DETERMINATION | SPECIFICATION | TEST METHOD |
| Description | white to off- white color powder without any lumps | In-House |
| Identification | Orange-red to deep blue color is produced after adding few drops of iodine. | In-House |
| Loss on drying | 15,0 % max. | IP, EU/BP, and USP |
| Sulphated ash | 0,6% max. | IP, EU/BP, and USP |
| SO2 | 50 mg/kg max. | IP, EU/BP, and USP |
| Foreign matter | Complies | IP, EU/BP, and USP |
| Oxidizing substances | 20 mg/kg max. | IP, EU/BP, and USP |
| Iron | 10 mg/kg max. | IP, EU/BP, and USP |
| рН | 4.5 - 7.0 | IP, EU/BP, and USP |
| Sieve grain size fraction -On 200 µm (70 mesh) | 0.1% max. | In-House |
| MICROBIAL LIMIT TEST: | | |
| Total Aerobic Microbial Count | 1000/g max | IP, EU/BP, and USP |
| Total Yeasts and Moulds Count | 100 /g max. | IP, EU/BP, and USP |
| Escherichia coli | Not detected in 1g | IP, EU/BP, and USP |
| Salmonellae | Not detected in 10g | IP, EU/BP, and USP |

Comments

- -Additional data
- -Methods used by NECROFILL may I.P, EU/BP, and USP or internal validated method which have been compared to the pharmacopeia monograph.