NECROGEL® C & C-LM (Low Moisture)

NECROGEL® C and C-LM partially pregelatinized starch is used as a filler for gelatin capsules and filler/binder for direct compression.
NECROGEL® C and C-LM combines the disintegration power of starch granules with the high cohesion and good compressibility of pregelatinized starch. Native starch is a common excipient for tablet and capsule manufacture. Due to its limited flow properties, native starch often requires the use of additional excipients and production steps such as granulation. A simple physical modification of starch (a partial pregelatinization) helps overcome these difficulties and results in a multifunctional excipient.
NECROGEL® C and C-LM is used in oral dosage forms in both pharmaceutical and nutraceutical applications, mainly for swallowable tablets and hard capsules. It is used as a filler/binder/disintegrant.

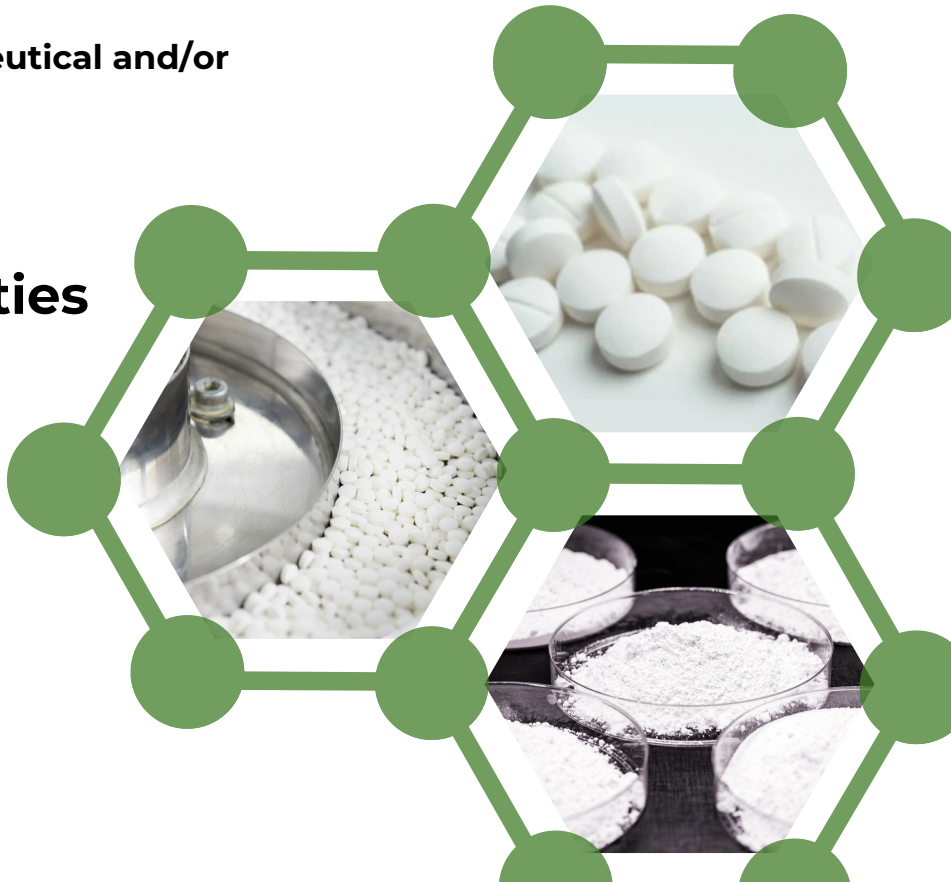
Key attributes: Free-flowing (standard grade), High density, Self-lubricated, Well adaptive to hard capsule filling. Medium cold water solubility

Applications

- **Oral Dosage for Pharmaceutical and/or Nutraceuticals**
  - **Swallowable tablet**
  - **Hard capsules**

Functional Properties

- **Excipient**
- **Binder**
  - **Disintegrant, Super Disintegrant**
  - **Filler or Filler/Binder**



NECROGEL® C LM

Partially-Pregelatinized Starch is prepared from Maize starch. CAS No. 9005-25-8		
DETERMINATION	**SPECIFICATION**	**TEST METHOD**
Description	White amorphous powder free from Lumps	IP, EU/BP, and USP
Identification	A Violet to Dark Blue color is produced by adding Iodine TS	IP, EU/BP, and USP
pH	4.5 - 7.0	IP, EU/BP, and USP
LOSS ON DRYING	Not more than 12%	IP, EU/BP, and USP
Solubility	It Semi-Swells in Cold Water	IP, EU/BP, and USP
SULFATED ASH(**)	NMT 0.5%	IP, EU/BP, and USP
RESIDUE ON IGNITION(**)	NMT 1.5%	IP, EU/BP, and USP
FOREIGN MATTER(*)	Complies	IP, EU/BP, and USP
OXIDISING SUBSTANCES	NMT 20 PPM	IP, EU/BP, and USP
Sieve Test	100 Mesh	IP, EU/BP, and USP
IRON(**)	20 ppm max.	IP, EU/BP, and USP
Limit of Sulphur Dioxide	NMT 0.005%	IP, EU/BP, and USP
MICROBIAL LIMIT TEST:		
-TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.	IP, EU/BP, and USP
-TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.	IP, EU/BP, and USP
-ESCHERICHIA COLI(**)	Not detected in 10g	IP, EU/BP, and USP
-SALMONELLA(**)	Not detected in 10g	IP, EU/BP, and USP

Comments

-Not intended for use in manufacture of parenteral dosage forms.
-Methods used by Necron may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.