PRODUCT

NECROGEL® C and 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

ADDITIONAL INFORMATION	
Manufacturer	Necron Pharma Speciality Products Pvt Ltd.
Quality	IP,EP, USP
Composition	Partially Pregelatinized starch
Dosage Form	Capsules, Tablets
Function	Filler-disintegrant for hard gelatin capsules. Also used as a flow aid in powder blends, highly effective binder-disintegrant in direct compression and wet granulation.

PRODUCT

NECROGEL® C LM

PARTIALLY- PREGELATINIZED STARCH
Pregelatinized starch is prepared from Maize starch.

Pregelatinized starch is prepared from Maize starch. CAS n° : 9005-25-8 **Specifications**		
APPEARANCE		White or off-white powder. It swells in cold water.
TESTS		
pH	I.P, EU/BP, and USP	4.5 - 7.0
OXIDISING SUBSTANCES	I.P, EU/BP, and USP	Complies
SULFUR DIOXIDE(**)	I.P, EU/BP, and USP	50 ppm max.
IRON(**)	I.P, EU/BP, and USP	20 ppm max.
FOREIGN MATTER(*)	I.P, EU/BP, and USP	Complies
LOSS ON DRYING	I.P, EU/BP, and USP	7.0 % max.
SULFATED ASH(**)	I.P, EU/BP, and USP	0.6 % max.
RESIDUE ON IGNITION(**)	I.P, EU/BP, and USP	0.5 % max.
HEAVY METALS(**)	ChP	20 mg/kg max.
PARTICLE SIZE : **- RESIDUE ON 200 MIC.**		7 % max.
MICROBIOLOGICAL VALUES: **- TOTAL AEROBIC MICROBIAL COUNT**		1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT **- ESCHERICHIA COLI(**)** **-SALMONELLA(**)**		100 CFU/g max. Not detected in 10g Not detected in 10g

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.

PRODUCT

NECROGEL® C LM

Caption

-"EP" stands for European Pharmacopoeia
-"NF" stands for National Formulary from USP-NF
-"ChP" stands for Chinese Pharmacopoeia
-(*) Compliance data - Tests not performed
-(**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP)** STARCH, PREGELATINIZED (1267)
- **National Formulary from USP-NF** Pregelatinized Starch
- **Chinese Pharmacopoeia (ChP)** Pregelatinized Starch

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent).

Storage

Expiry date Manufacturing date + 5 years (Stability Data On-Going), in its unopened packaging.
- The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
- We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity.
- Upon opening, use the product as quickly as possible to prevent moisture regain.

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process.
All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.
Notes : All the dates are formatted like YYYY/MM/DD.