

# PRODUCT

## NECROFILL®

NECROFILL® is a Waxy Maize 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.

These starches have a specific amylose amylopectin ratio that provides them a different behaviour compared to other maize starches (digestibility, viscosity, gelation properties, etc.) while offering the same stability.

Key attributes: High amylopectin starch, Improve starch paste stability.

### APPLICATIONS

Oral Dosage for Pharmaceutical and/or Nutraceuticals.

Swallowable tablet

Blends, Granules, Pellets Premix

### FUNCTIONAL PROPERTIES

Disintegrant, Super Disintegrant  
Filler or Filler/Binder

Carbohydrate Source

#### ADDITIONAL INFORMATION

Manufacturer	Necron Pharma Speciality Products Pvt Ltd.
Quality	IP,EP, USP
Composition	Maize starch
Dosage Form	Blends, Granules, Pellets Mix, Capsules, Tablets
Function	Carbohydrate Source, disintegrant/ super disintegrant, filler, Filler/Binder



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### Description (characters) Specifications

Native maize starch.

Maize starch is obtained from the caryopsis of *Zea mays* L.

<b>Aspect</b>		Very fine matt powder that creaks when pressed between the fingers.
<b>Colour</b>		White to slightly yellowish
<b>Solubility</b>		Practically insoluble in cold water and in ethanol 96%.
<b>Physical and chemical values (tests)</b>		
<b>Loss on drying</b>	I.P, EU/BP, and USP	15,0 % max.
<b>Sulphated ash</b>	I.P, EU/BP, and USP	0,6 % max.
<b>SO<sub>2</sub></b>	I.P, EU/BP, and USP	50 mg/kg max.
<b>Foreign matter</b>	I.P, EU/BP, and USP	Complies
<b>Oxidizing substances</b>	I.P, EU/BP, and USP	20 mg/kg max.
<b>Iron</b>	I.P, EU/BP, and USP	10 mg/kg max.
<b>pH</b>	I.P, EU/BP, and USP	4,0 - 7,0
<b>Sieve grain size fraction</b> - On 200 µm (70 mesh)	NECRON PHARMA	0,1 % max.
<b>Microbiological values</b>		
<b>Total aerobic microbial count</b>	I.P, EU/BP, and USP	1 000 /g max.
<b>Total yeasts and moulds count</b>	I.P, EU/BP, and USP	100 /g max.
<b>Escherichia coli</b>	I.P, EU/BP, and USP	Not detected in 1g
<b>Salmonellae</b>	I.P, EU/BP, and USP	Not detected in 10g

### 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.

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### *Legislation / specific regulations*

#### **Storage**

**Storage conditions** We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity.

Upon opening, use the product as quickly as possible to prevent moisture regain.

#### **Expiry date of the packed product**

Manufacturing date + 5 years (Stability Data On-Going), in its unopened packaging.

#### **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.

Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch and each criterion, the status of the analysis is indicated in the Certificate of Analysis.

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.

This Product Specification Sheet has been edited from a non-productive environment. Minor modifications could occur when the final productive environment will be used.

