PRODUCT

NECROGEL® PGS

It is a natural pregelatinized maize starch that has been specially developed as a binder for wet granulation. This excipient is dispersible and partially soluble in cold water and ready for use. The properties of NECROGEL® PGS result from a combination of the natural binding properties of Pregel starches and a controlled manufacturing process. The latter ensure this natural origin excipient of high stability reproducible binding properties during granulation and dissolution profile of actives in the final forms.

NECROGEL® PGS can be used in granules and swallowable forms in both pharmaceutical and nutraceutical applications.

Key attributes: Binder for high shear granulation
Fully pregelatinized starch.

APPLICATIONS

Oral Dosage for Pharmaceutical and/or Nutraceuticals.

Swallowable tablet

FUNCTIONAL PROPERTIES

Excipient

Binder

ADDITIONAL INFORMATION	
Manufacturer	Necron Pharma Speciality Products Pvt Ltd.
	IP,EP, USP
Composition	Pregelatinized Maize Starch
Dosage Form	Tablets
Function	Binder

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Pregelatinised 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
OXIDISING SUBSTANCES	I.P, EU/BP, and USP	Complies
SULFUR DIOXIDE(**)	I.P, EU/BP, and USP	50 ppm max.
SULFUR DIOXIDE(**)	I.P, EU/BP, and USP	80 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	15.0 % max.
LOSS ON DRYING	I.P, EU/BP, and USP	14.0 % max.
SULFATED ASH(**)	I.P, EU/BP, and USP	0.6 % max.
RESIDUE ON IGNITION(**)	I.P, EU/BP, and USP	0.5 % max.
PARTICLE SIZE : **- RESIDUE ON 315 MIC.**		20 % max.
- RESIDUE ON 80 MIC.		50 % min.
MICROBIAL CONTAMINATION:		
TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g max.
TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.
ESCHERICHIA COLI(**)		Absence in 10g.
SALMONELLA(**)		Absence in 10g.

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Comments

Methods used by Necron Pharma may be the Pharmacopoeia methods or internal validated methods which have been compared to the Pharmacopoeia methods.

Regarding any compliance referred to in the General Chapters of the Pharmacopoeias (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent), statements are available on request.

Storage

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

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

- * Compliance data - Tests not performed
- ** Monitoring plan

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.