

PRODUCT SPECIFICATIONS SHEET

LYCOAT® RS 780

Definition

Product Identifier

Product name: LYCOAT® RS 780

PREGELATINIZED HYDROXYPROPYL PEA STARCH (NF)
PREGELATINISED HYDROXYPROPYL STARCH (EP)

Specifications

A) CHARACTERS

APPEARANCE	White or slightly yellowish powder
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B) IDENTIFICATION

IDENTIFICATION TEST-A(*)	EP / NF	COMPLIES
IDENTIFICATION TEST-B(*)	EP / NF	COMPLIES
IDENTIFICATION TEST-C(*)	EP / NF	COMPLIES

C) TESTS

HYDROXYPROPYL VALUE	EP	0.5 - 7.0 %
HYDROXYPROPYL VALUE	NF	2.0 - 7.0 %
PH	EP / NF	4.5 - 8.0
OXIDIZING SUBSTANCES(H2O2)	EP / NF	20 mg/kg max.
SULFUR DIOXIDE	EP / NF	50 mg/kg max.
IRON	EP / NF	50 mg/kg max.
PROPYLENE GLYCOL	EP / NF	0.1 % max.
LOSS ON DRYING	EP / NF	15.0 % max.
SULFATED ASH	EP / NF	0.6 % max.
PARTICLE SIZE(SIEVE):		
- RESIDUE ON 500 microns		5 % max.
- RESIDUE ON 40 microns		95 % min.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	EP / NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP / NF	100 CFU/g max.
- ESCHERICHIA COLI	EP / NF	Not detected in 1g

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- SALMONELLA

EP

Not detected in 10g

Comments

- Not intended for use in manufacture of parenteral dosage forms.
- Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.
- Due to a few rare reported allergic reactions with pea (and their derived products), we strongly suggest to our customers to list the botanical origin of their pea derived products in their ingredient statement.

Caption

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

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia** STARCH, HYDROXYPROPYL PREGELATINISED
- **National Formulary from USP-NF** Pregelatinized Hydroxypropyl Pea 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 of the packaged product

manufacturing date + 5 years.

The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.

We recommend preserving 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.