

PRODUCT SPECIFICATIONS SHEET

GLYCOLYS®

Definition

Product Identifier

Product name: GLYCOLYS®

SODIUM STARCH GLYCOLATE (Type A): Sodium salt of a cross-linked partly O-carboxymethylated starch.
INCI: SODIUM CARBOXYMETHYL STARCH

Specifications

A) CHARACTERS

| | |
|------------|--|
| APPEARANCE | White or almost white powder, odourless, hygroscopic. |
| SOLUBILITY | Disperses in water to form a viscous colloidal solution. |
| . | Insoluble in ethanol and in ether. |

B) IDENTIFICATION

| | | |
|---------------------------|-----|----------|
| IDENTIFICATION TEST-1 (*) | ChP | COMPLIES |
| IDENTIFICATION TEST-2 (*) | ChP | COMPLIES |
| IDENTIFICATION TEST-3 (*) | ChP | COMPLIES |

C) TESTS

| | | |
|---------------------------------|-----|-----------------|
| ASSAY | ChP | 2.8 - 4.2 % |
| ACIDITY OR ALKALINITY (pH) | ChP | 5.5 - 7.5 |
| SODIUM GLYCOLATE | ChP | 2.0 % max. |
| SODIUM CHLORIDE (on DS) | ChP | 6.0 % max. |
| CHLOROACETIC ACID | ChP | 0.2 % max. |
| LOSS ON DRYING | ChP | 10.0 % max. |
| ETHANOL | | 6.0 % max. |
| IRON (**) | ChP | 0.002 % max. |
| HEAVY METALS (*) | ChP | 0.002 % max. |
| BROOKFIELD VISCOSITY | | 75 mPas max. |
| PARTICLE SIZE (Sieve) | | |
| - RESIDUE on 105 microns | | 2.0 % max. |
| MICROBIOLOGICAL VALUES: | | |
| - TOTAL AEROBIC MICROBIAL COUNT | | 1000 CFU/g max. |
| - TOTAL YEASTS AND MOULDS COUNT | | 100 CFU/g max. |

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- **ESCHERICHIA COLI(**)**

Not detected in 1g

- **SALMONELLA(**)**

Not detected in 10g

Indicatives Values

EXPANSION VOLUME

ChP

26 ml approx.

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.

Caption

- "ChP" stands for Chinese Pharmacopoeia

- (*) Compliance data - Tests not performed

- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- **Chinese Pharmacopoeia (ChP) SODIUM STARCH GLYCOLATE**

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, 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.



ROQUETTE

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Notes : All the dates are formatted like YYYY/MM/DD.