

GLYCOLYS® LOW PH

Definition

Product Identifier

Product name: GLYCOLYS® LOW PH

SODIUM STARCH GLYCOLATE (Type B): Sodium salt of a cross-linked partly O-carboxymethylated potato starch.

CAS n° : 9063-38-1

EINECS : 232-679-6

INCI: SODIUM CARBOXYMETHYL STARCH

Specifications

A) CHARACTERS

APPEARANCE

White or almost white,
Fine, free-flowing powder
Very hygroscopic

SOLUBILITY

Practically insoluble in methylene chloride. It gives a translucent suspension in water.

B) IDENTIFICATION

IDENTIFICATION TEST-A	EP	See Tests
IDENTIFICATION TEST-A(*)	USP-NF	COMPLIES
IDENTIFICATION TEST-B(*)	EP	COMPLIES
IDENTIFICATION TEST-B(*)	USP-NF	COMPLIES
IDENTIFICATION TEST-C(*)	EP	COMPLIES
IDENTIFICATION TEST-C(*)	USP-NF	COMPLIES
IDENTIFICATION TEST-D(*)	EP	COMPLIES
IDENTIFICATION TEST-D(*)	USP-NF	COMPLIES
IDENTIFICATION TEST-1(*)	JP	COMPLIES
IDENTIFICATION TEST-2(*)	JP	COMPLIES
IDENTIFICATION TEST-3(*)	JP	COMPLIES

C) TESTS

COMBINED SODIUM	EP / USP-NF / JP	2.0 - 3.4
pH	EP / USP-NF / JP	3.0 - 5.0



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SODIUM GLYCOLATE	EP / USP-NF / JP	2.0 % max.
SODIUM CHLORIDE	EP / USP-NF / JP	7.0 % max.
IRON(**)	EP / USP-NF / JP	20 mg/kg max.
HEAVY METALS(**)	USP-NF / JP	20 mg/kg max.
LOSS ON DRYING	EP / USP-NF / JP	10.0 % max.
ETHANOL	EP / USP-NF	6.0 % max.
ETHYL ACETATE(*)	EP / USP-NF	1500 mg/kg 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.
ESCHERICHIA COLI(**)		Not detected in 10g
SALMONELLA(**)		Not detected in 10g

Comments

Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Conformity

- **Current pharmacopeias** Ph.Eur. (type B)(0984), USP/NF (type B) and JP (type B)

Storage

STORAGE

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

SHELF LIFE

- **chemical stability** 5 years in its original 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.



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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.