

GLYCOLYS®

Definition

Product Identifier

Product name: GLYCOLYS®

SODIUM STARCH GLYCOLATE (Type A): 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	Ph.Eur.	See Tests
IDENTIFICATION TEST-A(*)	USP/NF	Conforms
IDENTIFICATION TEST-B(*)	Ph.Eur.	Conforms
IDENTIFICATION TEST-B(*)	USP/NF	Conforms
IDENTIFICATION TEST-C(*)	Ph.Eur.	Conforms
IDENTIFICATION TEST-C(*)	USP/NF	Conforms
IDENTIFICATION TEST-D(*)	Ph.Eur.	Conforms
IDENTIFICATION TEST-D(*)	USP/NF	Conforms
IDENTIFICATION TEST-1(*)	JP	Conforms
IDENTIFICATION TEST-2(*)	JP	Conforms
IDENTIFICATION TEST-3(*)	JP	Conforms

C) TESTS

COMBINED SODIUM	Ph.Eur.-USP/NF-JP	2.8 - 4.2
APPEARANCE OF SOLUTION	Ph.Eur.-JP	Conforms

GLYCOLYS®

pH	Ph.Eur.-USP/NF-JP	5.5 - 7.5
SODIUM GLYCOLATE	Ph.Eur.-USP/NF-JP	2.0 % max.
SODIUM CHLORIDE	Ph.Eur.-USP/NF-JP	7.0 % max.
IRON(**)	Ph.Eur.-USP/NF-JP	20 ppm max.
HEAVY METALS(**)	USP/NF-JP	20 ppm max.
LOSS ON DRYING	Ph.Eur.-USP/NF-JP	10.0 % max.
ETHANOL	Ph.Eur.-USP/NF	6.0 % max.
ETHYL ACETATE(*)	Ph.Eur.-USP/NF	1500 ppm max.
PARTICLE SIZE:		sieve
RESIDUE ON 105 MIC.		2.0 % max.
- MICROBIAL CONTAMINATION:		
TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g max.
SALMONELLA(**)		Absence in 10g.
ESCHERICHIA COLI(**)		Absence in 10g.
TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.

Comments

Methods used by Roquette may be Ph.Eur. or USP/NF or JP or internal validated method which have been compared to the pharmacopeia monograph.

Conformity

- **Current pharmacopeias** Ph.Eur. (type A)(0983), USP/NF (type A) and JP (type A)

Storage

STORAGE

Preserve in well-closed original containers, preferably protected from wide variations in 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

GLYCOLYS®

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.