

GLUCOSE® MONOHYDRATE GC

Definition

Product Identifier

Product name: GLUCOSE® MONOHYDRATE GC

GLUCOSE MONOHYDRATE(EP) - DEXTROSE MONOHYDRATE(USP)

CAS n° : 77938-63-7 / 14431-43-7

EINECS : 200-075-1

INCI: GLUCOSE

Specifications

A) CHARACTERS

APPEARANCE	White or almost white, crystalline powder.
SOLUBILITY	Freely soluble in water, very slightly soluble in ethanol (96%).

B) IDENTIFICATION

IDENTIFICATION TEST-A	USP/NF	Conforms.
IDENTIFICATION TEST-A	Ph.Eur.	Conforms.
IDENTIFICATION TEST-B	Ph.Eur.-USP/NF	See tests.
IDENTIFICATION TEST-C	USP/NF	See tests.
IDENTIFICATION TEST-E	Ph.Eur.	See tests.

C) TESTS

APPEARANCE OF SOLUTION	Ph.Eur.-USP/NF	Conforms
CONDUCTIVITY	Ph.Eur.-USP/NF	20 microS/cm-1
RELATED SUBSTANCES :		
- SUM OF IMPURITIES A AND B	Ph.Eur.-USP/NF	0.4 % max.
- IMPURITY C	Ph.Eur.-USP/NF	0.2 % max.
- IMPURITY D	Ph.Eur.-USP/NF	0.15 % max.
- UNSPECIFIED IMPURITIES	Ph.Eur.-USP/NF	0.10 % max.
- TOTAL	Ph.Eur.-USP/NF	0.5 % max.
DEXTRIN	Ph.Eur.-USP/NF	Conforms
SOLUBLE STARCH, SULFITE	Ph.Eur.-USP/NF	15 ppm max.

PRODUCT SPECIFICATION SHEET

GLUCOSE® MONOHYDRATE GC

WATER	Ph.Eur.-USP/NF	7.5 - 9.5 %
ASSAY	Ph.Eur.-USP/NF	97.5 - 102.0 %
HEAVY METALS(*)	USP/NF	5% max.
PARTICLE SIZE:		sieve
- RESIDUE ON 500 MIC. (35 MESH)		30 % max.
- RESIDUE ON 315 MIC. (45 MESH)		20 - 70 %
- RESIDUE ON 200 MIC.		60 % 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.

Comments

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

Conformity

- **Current pharmacopoeias** Ph.Eur.(0178) and USP/NF

Storage

SHELF LIFE

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

STORAGE

Preserve in well-closed containers, preferably protected from wide variations in temperature and humidity.

- * 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.