

PRODUCT SPECIFICATION SHEET GLUCOSE SYRUP 3883

Definition

Product identifier

Product name: GLUCOSE SYRUP 3883

CAS-No.	8029-43-4
EC No.	232-436-4

Specifications

Description (characters)

Glucose syrup.
Aqueous solution containing a mixture of glucose, oligosaccharides and polysaccharides obtained by hydrolysis of starch.

Aspect	Syrupy liquid
Colour	Colourless to yellowish
Odour	Neutral
Taste	Sweet
Solubility	Miscible with water.

Identification

Identification test A	EP	Complies
Identification test A	NF	Complies
Identification test B	EP	Complies
Identification test C	EP	Complies
Identification test D	EP	Complies

Physical and chemical values (tests)

Dry substance (Roquette table)	ROQUETTE	82,5 - 83,5 %(w/w)
Loss on drying	EP	30,0 %(w/w) max.
Water content	NF	21,0 %(w/w) max.
Dextrose equivalent	EP, NF	36 - 39 %(w/w)
pH	EP	4,0 - 6,0
Sulphated ash	EP, NF	0,5 %(w/w) max.
SO2	EP	20 mg/kg max.
Soluble starch	NF	Complies
Sulfites	NF	Complies
Acidity	NF	0,60 ml max.

Microbiological values

Total aerobic microbial count	1 000 /g max.
Total yeasts and moulds count	100 /g max.
Escherichia coli	Not detected in 1g

Additional data

Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods.

Caption :

- EP stands for European Pharmacopoeia
- NF stands for National Formulary from USP - NF

Colour of product is likely to change with time and temperature.

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:

- European Pharmacopoeia (EP) : GLUCOSE SYRUP (1330)
- National Formulary from USP-NF : LIQUID GLUCOSE

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

Storage

Storage conditions	The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
Storage conditions for PACK material	We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain. We recommend a storage temperature around 50 - 60°C and a fast use after delivery.
Expiry date of the packed product	Manufacturing date + 3 years, in its unopened packaging.

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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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.

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