

GLUCIDEX® IT 38

Definition

Product Identifier

Product name: GLUCIDEX® IT 38

GLUCOSE, LIQUID, SPRAY-DRIED (EP)

Mixture of glucose, disaccharides and polysaccharides, obtained by the partial hydrolysis of starch.

CAS No. 68131-37-3

Specifications

A) CHARACTERS

APPEARANCE

White or almost white powder.

SOLUBILITY

Freely soluble in water.

B) IDENTIFICATION

IDENTIFICATION TEST-A

EP Complies.

IDENTIFICATION TEST-B

EP Complies.

IDENTIFICATION TEST-C

EP Complies.

IDENTIFICATION TEST-D

EP Complies.

C) TESTS

pH

EP 4.0 - 7.0

SO₂

EP 20 ppm max.

LOSS ON DRYING

EP 6.0 % max.

SULFATED ASH

EP 0.5 % max.

DEXTROSE EQUIVALENT

EP 36 - 40

PARTICLE SIZE (SIEVE):

- RESIDUE ON 500 microns

5 % max.

- RESIDUE ON 40 microns

95 % min.

MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT

1000 cfu/g max.

- TOTAL YEASTS & MOULDS COUNT

100 cfu/g max.

- ESCHERICHIA COLI

Not detected in 10g

- SALMONELLA

Not detected in 10g

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Indicatives Values

Poured bulk density : 500 g/l approx.

Particle mean diameter : 180 microns approx.

Comments

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

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP)

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.

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

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.