

## ROQUETTE GLUCOSE SYRUP 4280

### Definition

#### Product Identifier

**Product name:** ROQUETTE GLUCOSE SYRUP 4280

GLUCOSE, LIQUID (EP) - LIQUID GLUCOSE (NF)

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

CAS No. 8029-43-4 / 8027-56-3

### Specifications

#### A) CHARACTERS

APPEARANCE	Syrupy liquid
COLOUR	Colourless to yellowish
TASTE	Sweet
ODOUR	Neutral
SOLUBILITY	Miscible in water

#### B) IDENTIFICATION

IDENTIFICATION TEST-A	USP-NF	Complies
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 - 6.0
ACIDITY(*)	USP-NF	0.60 ml max
SO <sub>2</sub>	EP	20 ppm max.
SULFITE(*)	USP-NF	Complies
DRY SUBSTANCE	ROQUETTE	79.9 - 80.9 %
LOSS ON DRYING(*)	EP	30.0 % max.
WATER CONTENT(*)	USP-NF	21.0 % max.
DEXTROSE EQUIVALENT	EP/USP-NF	40 - 44
SULPHATED ASH(*)	EP/USP-NF	0.5 % max.
STARCH(*)	USP-NF	Complies

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### MICROBIOLOGICAL VALUES:

- TOTAL COUNT(**)	EP/USP-NF	1000 CFU/g max
- YEASTS AND MOULDS(**)	EP/USP-NF	100 CFU/g max
- E.COLI(**)	EP/USP-NF	Not detected in 1g

### Comments

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

The colour of the product is likely to change with time and temperature.

ROQUETTE's liability is limited to reception of the bulk product at the customer's site.

The chemical stability of the bulk product depends on the customer's unloading and storage conditions.

### Conformity

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#### Conforms to the current edition of

- European Pharmacopoeia (EP)
- National Formulary (NF)

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent).

### Storage

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Store bulk material in a closed and integral silo / tank.

We recommend a bulk storage temperature around 50 - 60°C and a fast use after delivery.

**For packaged material only, Expiry Date** MD +5 years, in its unopened packaging.

- \* Compliance data - Tests not performed
- \*\* Monitoring plan

### Disclaimer

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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.