

PRODUCT SPECIFICATION SHEET
XYLISORB® 300 - XYLITOL

Definition

Product identifier

Product name: XYLISORB® 300 - XYLITOL
INCI: XYLITOL

Specifications

Description (characters)

meso -XYLITOL

| | |
|---------------|--------------------------------|
| Aspect | Crystalline powder or crystals |
| Colour | White or almost white |

Identification

| | | |
|------------------------------|----|----------|
| Identification test 1 | JP | Complies |
| Identification test 2 | JP | Complies |

Physical and chemical values (tests)

| | | |
|--------------------------------|----|----------------|
| Loss on drying | JP | 1,0 % max. |
| Xylitol content (on DS) | JP | 98,0 % min. |
| Totals sugars (as is) | JP | complies |
| pH | JP | 5,0 – 7,0 |
| Melting point | JP | 93,0 – 95,0 °C |
| Appearance of solution | JP | complies |
| Residue on Ignition | JP | 0,1 % max. |
| Chloride | JP | 50 mg/kg max. |
| Sulphate | JP | 60 mg/kg max. |
| Arsenic | JP | 1,3 mg/kg max. |
| Nickel | JP | complies |
| Heavy metals | JP | 5 mg/kg max. |

Particle size (Sieve) :

| | |
|--------------------------|-----------|
| - Residue on 500 microns | 2 % max. |
| - Residue on 315 microns | 20 % max. |
| - Residue on 100 microns | 60% min. |

Microbiological values

| | |
|-------------------------------|---------------------|
| Total aerobic microbial count | 1000 CFU/g max. |
| Total yeasts and moulds count | 100 CFU/g max. |
| Escherichia coli | Not detected in 1g |
| Salmonellae | Not detected in 10g |

Additional data

Comments

Not intended for use in manufacture of parenteral dosage forms.

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

Caption:

- "JP" stands for Japanese Pharmacopoeia

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph:

- Japanese Pharmacopoeia: Xylitol

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

Storage

The product durability may vary according to packaging type and manufacturing plant.
Proper information is shown on labelling and CoA.

Storage conditions - We recommend preserving the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity.
Upon opening, use the product as quickly as possible to prevent moisture regain.

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.

Notes:

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

This Product Specification Sheet has been edited from a non-productive environment. Minor modifications could occur when edited from the final productive environment.