

XYLISORB® 300

Definition

Product Identifier

Product name: XYLISORB® 300

MESO-XYLITOL

CAS no. : 87-99-0

INCI: XYLITOL

Specifications

A) CHARACTERS

APPEARANCE	White, crystals or powder
ODOUR	Odorless
TASTE	Sweet

B) IDENTIFICATION

IDENTIFICATION TEST-1	JP	COMPLIES
IDENTIFICATION TEST-2	JP	COMPLIES

C) TESTS

pH	JP	5.0 - 7.0
MELTING POINT	JP	93.0 - 95.0 ° C
ASPECT IN SOLUTION	JP	Clear, colourless
CHLORIDE	JP	0.005 % max.
SULFATE	JP	0.006 % max.
HEAVY METALS	JP	5 mg/kg max.
NICKEL	JP	COMPLIES
ARSENIC	JP	1.3 mg/kg max.
SUGARS	JP KMnO4 0.02 mol/l	1.0 ml max.
LOSS ON DRYING	JP	1.0 % max.
RESIDUE ON IGNITION	JP	0.1 % max.
ASSAY	JP	98.0 % min.
PARTICLE SIZE (sieve)		
- RESIDUE ON 500 microns		2 % max.
- RESIDUE ON 315 microns		20 % max.
- RESIDUE ON 100 microns		60 % min.

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MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 10g
- SALMONELLA	Not detected in 10g

Comments

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

Not intended for use in manufacture of parenteral dosage forms.

Conformity

Conforms to the current edition of

- Japanese Pharmacopoeia (JP)

Storage

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