

XYLISORB® XTAB 400 - XYLITOL,CMC

Definition

Product Identifier

Product name: XYLISORB® XTAB 400 - XYLITOL,CMC

XYLISORB® XTAB 400 IS A COMPOUND OF:

- APPROX 98% OF XYLITOL
- APPROX 2% OF SODIUM CARBOXYMETHYL CELLULOSE

Specifications

A) CHARACTERS

APPEARANCE	Off-white and odourless powder
TASTE(*)	Sweet and cool

B) TESTS

XYLITOL on DS	98 % min.
Na CARBOXYMETHYL CELLULOSE on DS	1 % min.
REDUCING SUGARS(as is)	0.2 % max.
LEAD(**)	0.5 mg/kg max.
NICKEL(**)	1 mg/kg max.
WATER CONTENT	0.5 % max.
RESIDUE ON IGNITION(*)	1 % max.
PARTICLE-SIZE (Sieve)	
- RESIDUE on 800 microns	5 % max.
- RESIDUE on 100 microns	90 % 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
- SALMONELLA(**)	Not detected in 10g

Indicatives Values

MEAN DIAMETER	400 microns approx.
BULK DENSITY	0.5 - 0.7 Kg/L

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pH(at 50% W/W)

5.0 - 7.0

Comments

Not intended for use in manufacture of parenteral dosage forms.

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

Caption

-(*) Compliance data - Tests not performed

-(**) Monitoring plan

Conformity

Raw materials

- **XYLITOL** European Pharmacopoeia (1381) and

National Formulary from USP-NF

- **SODIUM CARBOXYMETHYL CELLULOSE** European Pharmacopoeia (0472) and

National Formulary from USP-NF

Storage

Expiry date Manufacturing date + 5 years, in its unopened packaging.

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

-We recommend to preserve 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.

-Due to its fine particle size, this product is liable to become compacted.

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.