ROQUETTE
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PRODUCT SPECIFICATIONS SHEET

KLEPTOSE® DC-BETA CYCLODEXTRIN

Definition

Product Identifier

Product name: KLEPTOSE® DC-BETA CYCLODEXTRIN

BETACYCLODEXTRIN
Betacyclodextrin is a nonreducing cyclic compound composed of seven alpha-(1-4) linked D-glucopyranosyl units.
INCI : CYCLODEXTRIN

Specifications

A) CHARACTERS

APPEARANCE	White or almost white, amorphous or crystalline hygroscopic powder.
SOLUBILITY	Sparingly soluble in water and in propylene glycol, practically insoluble in anhydrous ethanol and in methylene chloride.

B) PHYSICO-CHEMICAL VALUES

IDENTIFICATION TEST-A	EP	COMPLIES
IDENTIFICATION TEST-A (*)	NF	COMPLIES
IDENTIFICATION TEST-B	EP / NF	COMPLIES
IDENTIFICATION TEST-C (*)	EP	COMPLIES
IDENTIFICATION TEST-C	NF	COMPLIES
IDENTIFICATION TEST-D (*)	NF	COMPLIES

C) TESTS

BETA CYCLODEXTRIN ON DS	EP / NF	98.0 - 102.0 %
APPEARANCE IN SOLUTION	EP / NF	COMPLIES
pH	EP / NF	5.0 - 8.0
SPECIFIC OPTICAL ROTATION	EP / NF	+160° to +164°
REDUCING SUGARS	EP / NF	0.2 % max.
LIGHT-ABSORBING IMPURITIES:		
230 nm - 350 nm	EP / NF	0.10 max.
350 nm - 750 nm	EP / NF	0.05 max.
RELATED SUBSTANCES:		
- ALPHA CYCLODEXTRIN	EP / NF	0.25 % max.

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- GAMMA CYCLODEXTRIN	EP / NF	0.25 % max.
- SUM OF OTHER IMPURITIES	EP / NF	0.5 % max.
RESIDUAL SOLVENTS:		
- TRICHLOROETHYLENE(*)	EP	10 mg/kg max.
- TRICHLOROETHYLENE	ROQUETTE	1 mg/kg max.
LOSS ON DRYING(*)	EP	16.0 % max.
WATER CONTENT	NF	14.0 % max.
SULPHATED ASH	EP	0.1 % max.
RESIDUE ON IGNITION	NF	0.1 % max.
PARTICLE SIZE (sieve)		
- RESIDUE ON 40 microns		60 % min.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	NF	100 CFU/g max.
- ESCHERICHIA COLI	NF	Not detected in 1g
- SALMONELLA	NF	Not detected in 10g

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

-"EP" stands for European Pharmacopoeia

-"NF" stands for National Formulary from USP-NF

-(*) Compliance data - Tests not performed

Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia (EP) BETADEX (1070)

- National Formulary from USP-NF BETADEX

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

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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.

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.