ROQUETTE
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PRODUCT SPECIFICATIONS SHEET

KLEPTOSE® HPB PARENTERAL GRADE

Definition

Product Identifier

Product name: KLEPTOSE® HPB PARENTERAL GRADE

HYDROXYPROPYLBETADEX is a partially substituted poly(hydroxypropyl) ether of betadex.
INCI : HYDROXYPROPYL CYCLODEXTRIN

Specifications

A) CHARACTERS		
APPEARANCE	White or almost white, amorphous or crystalline powder.	
SOLUBILITY	Freely soluble in water and in propylene glycol.	
B) IDENTIFICATION		
IDENTIFICATION-TEST A	EP / NF	COMPLIES
IDENTIFICATION-TEST B	EP / NF	COMPLIES
C) TESTS		
APPEARANCE IN SOLUTION	EP / NF	COMPLIES
CONDUCTIVITY	EP / NF	200 micro.S/cm max.
RELATED SUBSTANCES		
-IMPURITY A / BETADEX(on DS)	EP / NF	1.5 % max.
-IMPURITY B / PROPYLENE GLYCOL(on DS)	EP / NF	2.5 % max.
-SUM OF IMPURITIES OTHER THAN A(on DS)	EP	1.0 % max.
-ANY OTHER IMPURITY(on DS)	NF	0.25 % max.
-TOTAL OF OTHER IMPURITIES(on DS)	NF	1 % max.
LOSS ON DRYING	EP / NF	10.0 % max.
MOLAR SUBSTITUTION	EP / NF	0.40 - 1.50
PROPYLENE OXIDE(**)	NF	0.0001 % max.
PARTICLE SIZE (Sieve)		
- RESIDUE ON 315 microns		20 % max.
- RESIDUE ON 100 microns		50 % min.
MICROBIOLOGICAL VALUES:		
-TOTAL AEROBIC MICROBIAL COUNT	EP / NF	100 CFU/g max.

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-TOTAL YEASTS AND MOULDS COUNT	EP / NF	100 CFU/g max.
-ESCHERICHIA COLI	EP	Not detected in 10g
-SALMONELLA	EP	Not detected in 10g
BIOLOGICAL VALUES:		
- BACTERIAL ENDOTOXINS	EP / NF	10 EU/g max.

Indicatives Values

MOLAR SUBSTITUTION NOMINAL VALUE	EP / NF	0.62
MOLAR SUBSTITUTION (MS)	EP / NF	0.58 - 0.68

Comments

This substance is suitable for use in the manufacture of parenteral preparations.

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

Caption

-"EP" stands for European Pharmacopoeia

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

-(**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia (EP) HYDROXYPROPYLBETADEX (1804)

- National Formulary from USP-NF HYDROXYPROPYL BETADEX

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

Storage

RETEST DATE Manufacturing date + 3 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.

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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.