

KLEPTOSE® HPB-LB PARENTERAL GRADE

Definition

Product Identifier

Product name: KLEPTOSE® HPB-LB PARENTERAL GRADE

HYDROXYPROPYLBETADEX is a partially substituted poly(hydroxypropyl) ether of betadex.

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/USP-NF	COMPLIES
IDENTIFICATION TEST-B	EP/USP-NF	COMPLIES
IDENTIFICATION TEST(*)	ChP	COMPLIES

C) TESTS

APPEARANCE IN SOLUTION	EP/NF/ChP	COMPLIES
CONDUCTIVITY	EP/USP-NF	200 microS/cm max.
CHLORIDES	ChP	0.05 % max.
pH	ChP	5.0 - 7.5
RELATED SUBSTANCES:		
-IMPURITY A / BETADEX(on DS)	EP/USP-NF	1.5 % max.
-BETADEX	ChP	0.5 % max.
-BETADEX(on DS)	ROQUETTE	0.3 % max.
-IMPURITY B / PROPYLENE GLYCOL(on DS)	EP/USP-NF	2.5 % max.
-SUM OF IMPURITIES OTHER THAN A(on DS)	EP	1.0 % max.
-PROPYLENE GLYCOL(on DS)	ChP	0.5 % max.
-ANY OTHER SINGLE IMPURITY(on DS)	USP-NF	0.25 % max.
-ANY OTHER SINGLE IMPURITY(on DS)	ROQUETTE	0.1 % max.
-TOTAL OF OTHER IMPURITIES THAN A,B(onDS)	USP-NF	1 % max.
-TOTAL OF OTHER IMPURITIES THAN A,B(onDS)	ROQUETTE	1.0 % max.
RESIDUE ON IGNITION	ChP	0.2 % max.
HEAVY METALS	ChP	10 mg/kg max.

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LOSS ON DRYING	EP/USP-NF	10.0 % max.
WATER	ChP	6.0 % max.
ASSAY ON DS(*)	ChP	19.6 - 26.3 %
MOLAR SUBSTITUTION	EP/USP-NF	0.40 - 1.50
MOLAR SUBSTITUTION	ROQUETTE	0.50 - 0.71
PROPYLENE OXIDE(**)	USP-NF	1 mg/kg max.
MICROBIOLOGICAL VALUES:		
-TOTAL AEROBIC MICROBIAL COUNT	EP/USP-NF	100 CFU/g max.
-TOTAL YEASTS AND MOULDS COUNT	EP/USP-NF	100 CFU/g max.
-ESCHERICHIA COLI	EP	Not detected in 10g
-SALMONELLA	EP	Not detected in 10g
BIOLOGICAL VALUES:		
-BACTERIAL ENDOTOXINS	EP/USP-NF	<10 EU/g

Indicative Values

MOLAR SUBSTITUTION NOMINAL VALUE	EP/USP-NF	0.69
MOLAR SUBSTITUTION	EP/USP-NF	0.62 - 0.76
PARTICLE SIZE (Sieve):		
-RESIDUE ON 315 microns		20 % approx.
-RESIDUE ON 100 microns		50 % approx.

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 pharmacopoeia monograph.

Caption

- "EP" stands for European Pharmacopoeia
- "USP-NF" stands for USP-NF Pharmacopoeia
- "ChP" stands for Chinese Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP) HYDROXYPROPYLBETADEX (1804)**



PRODUCT SPECIFICATIONS SHEET

KLEPTOSE® HPB-LB PARENTERAL GRADE

- **USP-NF Pharmacopeia** HYDROXYPROPYL BETADEX
- **Chinese Pharmacopoeia (ChP)** HYDROXYPROPYL BETADEX

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.

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.