



KLEPTOSE® HPB-LB parenteral grade

a multi-compendial excipient for efficient drug delivery



Roquette's **KLEPTOSE® HPB-LB** is a new grade of hydroxypropyl β -cyclodextrin (HPBCD) excipient for use in parenteral applications. Meeting the highest purity standards across the world and following the principles of GMP, **KLEPTOSE® HPB-LB** parenteral grade facilitates the registration of pharmaceutical products in multiple target markets.



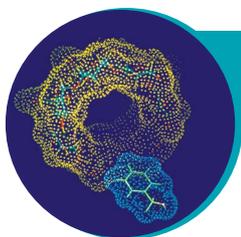
ONE SOLUTION: GLOBAL COMPLIANCE

KLEPTOSE® HPB-LB parenteral grade is a multi-compendial product that complies with European and U.S. Pharmacopeia, and has standards that not only comply with but are even higher than Chinese Pharmacopeia. Part of the wider **KLEPTOSE®** product range, **KLEPTOSE® HPB-LB** supports local and global pharmaceutical manufacturers in overcoming registration filing challenges in China, as well as the rest of the world, without the need to develop multiple drug solutions. This can accelerate speed to market and provides a competitive advantage.



A VERSATILE EXCIPIENT FOR THE PHARMA INDUSTRY

Molecular encapsulation with **KLEPTOSE® HPB-LB** provides active substance stabilization improvement against light and oxidation in parenteral preparations, however, it can also be used as a solubility enhancer.



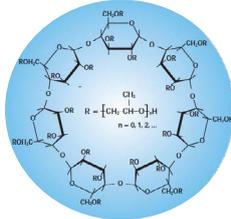
UNIQUE MOLECULAR STRUCTURE

The HPBCD molecule is a torus shaped ring with a polar hydrophilic outside and an apolar hydrophobic cavity. This structural feature is due to the spatial distribution of its external hydrophilic properties. As a consequence of this particular structure, HPBCD encapsulates or entraps guest molecules to form the so-called inclusion compounds when in an aqueous solution. Hydroxypropyl β -cyclodextrins are purified polydisperse products resulting from the controlled reaction of propylene oxide and native β -cyclodextrins under base catalysis.



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The secondary OH groups on C-2 and C-3 are on the opposite edge, which gives HPBCD its external hydrophilic properties. The inside of the HPBCD ring is composed of a surface of hydrophobic C-3 and C-5 hydrogens as well as glycosidic ether-like oxygen.

The molar substitution (MS) is the average number of hydroxypropyl groups per anhydroglucose unit. The degree of substitution (DS) is the number of hydroxypropyl groups per molecule of β -cyclodextrin and is obtained by multiplying the MS by 7. **KLEPTOSE® HPB-LB** is a composite product with a specific substitution pattern. The consistency of this substitution pattern is guaranteed by the manufacturing conditions applied by Roquette. The MS range of **KLEPTOSE® HPB-LB** complies with the EP/USP requirement (0.40-1.50) and ChP requirement (0.50-0.71.)



VALUE-ADDED BENEFITS

- Multi-compendial, enables access to the global market
- High aqueous solubility
- Encapsulation process versatility
- Encapsulation efficiency of a wide range of molecules
- Stability at high temperature allowing terminal steam sterilization
- Stability at hydrolysis in different pH range
- Production and quality systems following GMP principles
- Fiber-free packaging, with tamper- proof evidence
- Enhanced packaging with recyclable materials



A TRUSTED PARTNER

Roquette has pioneered the industrial development of cyclodextrins with its **KLEPTOSE®** range of β -cyclodextrins. As a leading integrated supplier offering full traceability and supply chain security, you have peace of mind that your pharmaceutical applications meet the highest quality and regulatory requirements. Improving patient health is your top priority. Ensuring your formulations' safety is ours. That's why we commit to securing the highest purity ingredients for use in reliable oral and parenteral preparations.

For further details, or to learn more about **KLEPTOSE® HPB-LB**, please get in touch with our experts.

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or visit www.roquette.com



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