The Emprove® Program

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time and resource intensive. Our Emprove® Program helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To help you optimize your process, our Emprove® Program provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. The Emprove® Program is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Ordering Information

Cyclodextrin HPB EMPROVE® EXPERT Ph.Eur., NF

Cat. No.	Pack Size	Packaging
1.42020.0050	50 g	Plastic bottle in corrugated box
1.42020.2500	2.5 kg	Plastic bottle in corrugated box

The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: **EMDMillipore.com**

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice does not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

unlock the possibilities

Enhancing Solubility and Stability with Cyclodextrins

Formulation Product Finder App

Find the right product for your application with our Formulation Product Finder App at:

EMDMillipore.com/formulationapp

SAFC®
Pharma & Biopharma Raw Material Solutions

cyclodextrin for enhanced possibilities.

Insufficient stability and low solubility are frequent hurdles during pharmaceutical development as they directly impair drug bioavailability and, in consequence, the efficacy and success of the final drug product. Aqueous formulations, e.g. for oral or parenteral application, bear the risk of chemical degradation for compounds prone to hydrolysis or oxidation. In addition, as newly developed compounds are becoming more and more complex and hydrophobic, the need for approaches to overcome both stability and solubility issues is continuously increasing.

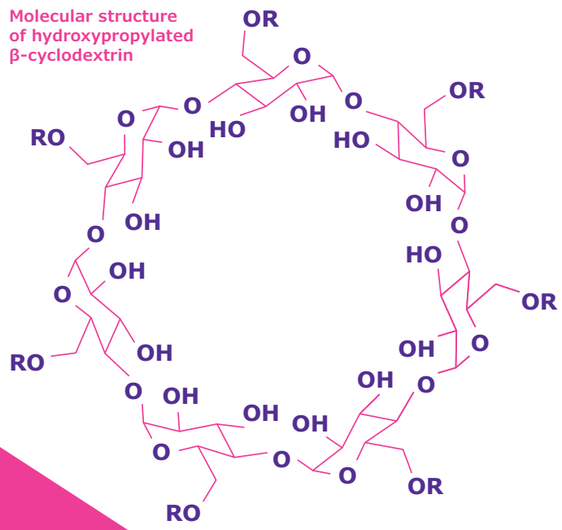
Cyclodextrins can help to overcome these hurdles. First discovered as early as in the 19th century, these natural molecules have become a frequently used type of excipients in both pharmaceutical and biopharmaceutical formulations. Due to their unique characteristics, cyclodextrins can exert a broad range of functions such as protection of compounds against chemical degradation, reduction of protein aggregation, increase of drug solubility as well as masking of odors and tastes.

Our hydroxypropylated beta-cyclodextrin (Cyclodextrin HPB) will help you ease your mind, regardless of your desired application or dosage form. It is part of our Emprove® Expert portfolio, specifically optimized to address the demands of high-risk applications.

Benefits

- Increases solubility and stability
- Enhances bioavailability
- Masks odors and tastes
- Reduces aggregation behavior of biologic APIs
- Emprove® Expert product with low endotoxin levels for high-risk applications

Molecular structure of hydroxypropylated β-cyclodextrin

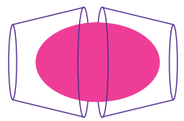


HP-β-CD
(R=CH_3-CH(OH)-CH_2-)

Mode of Action

Cyclodextrins are cyclic oligosaccharides derived from natural starch. The α-1,4-D-glucopyranoside units are arranged in the form of a hollow cone with a hydrophilic exterior and a hydrophobic cavity. Within this cavity, cyclodextrins can “complex” hydrophobic, poorly water-soluble active pharmaceutical ingredients (APIs), forming an API-cyclodextrin inclusion complex. This “host-guest” interaction is reversible, and the API is easily released once administered to the body.

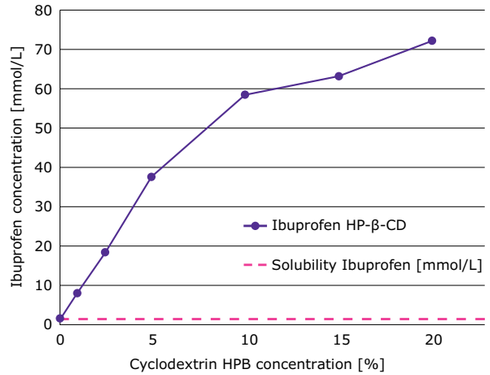
API-cyclodextrin complex with the API in the cyclodextrin cavity



Increased API Solubility

API-cyclodextrin complexes usually show strongly improved solubility, thus rendering our Cyclodextrin HPB an excellent choice for bioavailability enhancement of poorly water-soluble APIs. As shown in the figure on the right, solubility of the model API Ibuprofen was significantly increased if complexed with Cyclodextrin HPB. At an API:cyclodextrin ratio of 1:10, Ibuprofen solubility was approx. 80 times higher in comparison to pure API.

Solubility of Ibuprofen as a function of Cyclodextrin HPB concentration. Experimental conditions: Incubation of 100 mmol/L Ibuprofen with different concentrations of Cyclodextrin HPB (0 – 20 %) at pH 5.0 (50 mmol/L acetate buffer) for 24 h at 25 °C; centrifugation at 16,000 rpm; determination of Ibuprofen concentration in supernatant by HPLC.



Improved API Stability

Cyclodextrin HPB is also an excellent option for increasing the stability of your API. As the encapsulated parts of the API are better protected against hydrolysis or oxidation, chemical degradation is reduced. In addition, the API-cyclodextrin complex can prevent API-excipient as well as API-API interactions, therefore reducing aggregation behavior of biologic APIs.

Broad Application Range

Due to their shielding effects, cyclodextrins can help minimizing or even preventing gastrointestinal and ocular irritation. They can be applied to reduce undesired characteristics of the API, such as unpleasant taste or odor, or toxicity. In addition, cyclodextrins can also be used to convert liquid or oily APIs into a free-flowing, solid powder which can then be processed into tablets.

The application of Cyclodextrin HPB is not limited to a specific formulation type or administration route. In fact, the application range of this product is very wide: you can use it in liquid, semi-solid and solid formulations, and marketed products exist intended for oral, dermal, rectal, ocular and parenteral application.

Safety and Purity

Cyclodextrin HPB has been used in pharmaceutical products for decades and is cited in the FDA’s list of Inactive Pharmaceutical Ingredients. Numerous safety reports as well as dosing thresholds for different application routes exist. Parenterally administered cyclodextrins are usually renally excreted intact without metabolization and oral availability of Cyclodextrin HPB is reported as very low. In fact, Cyclodextrin HPB can be applied to reduce adverse effects of APIs and, thus, improve safety of the final dosage form.