CYCLOLAB

The Cyclodextrin Company

Getting the best out of Cyclodextrins

CYCLOLAB Ltd.

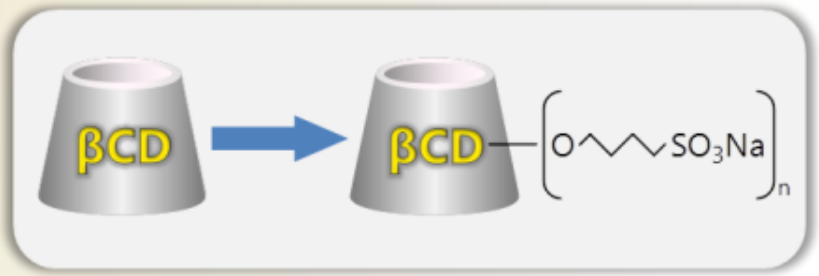
Dexolve™

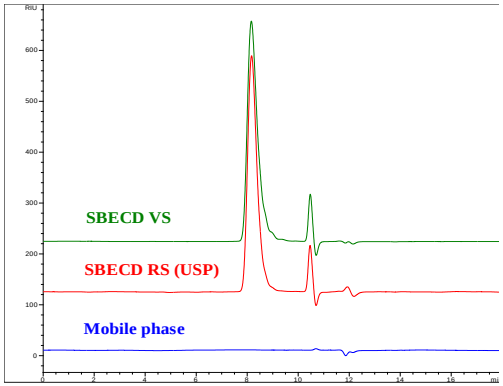
the USP and EP compliant SBECD of Cyclolab Ltd

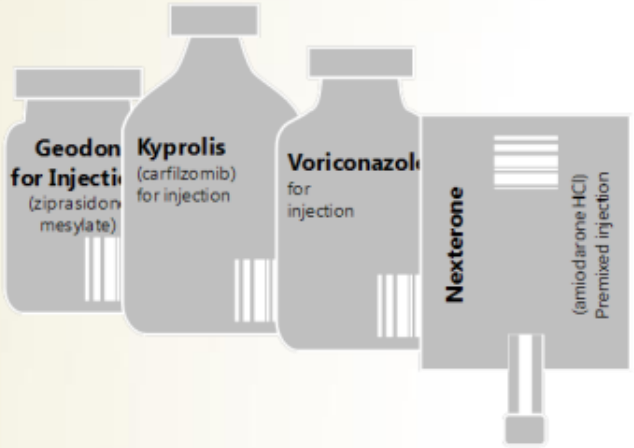
Dexolve™

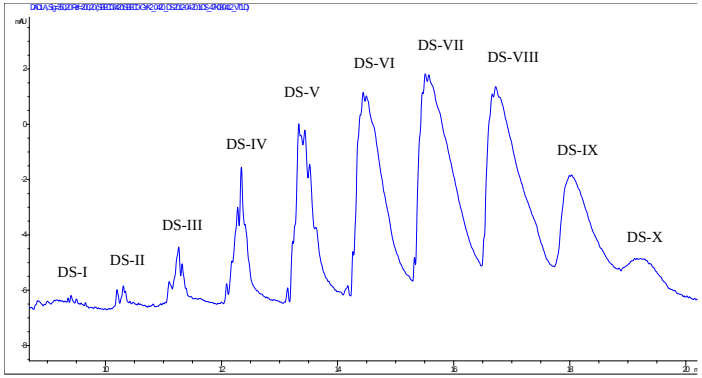
for Improved Pharmaceutical Formulations

Cyclolab Ltd is the producer of the first generic USP and EP-conform Betadex Sulfobutyl Ether Sodium (SBECD = Dexolve™)









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CYCLOLAB
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Homepage: www.cyclolab.hu
VAT No.: HU 10678970

ISO 9001

FDA REGISTERED

DMF No. 21922

GMP

OGYÉI/57792-7/2018

Drug master file of the excipient
Sulfobutyl-ether-β-cyclodextrin sodium salt
(SBECD)

CFDA China Food and Drug Administration

Document No.: DMF-SBECD-v02

CANADA HEALTH

EudraGMDP

DMF No. F20180001741

DMF No. 2009-080

OGYÉI/30391-2/2018

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Why use Dexolve? Possibilities…

- Significant solubility enhancement (10 to 100,000 fold)
- Improvement of chemical stability
- Increased bioavailability, facilitated delivery
- Reduced aggregation
- Moderate irritation or reduced side-effects
- Maximized patient safety, complete renal elimination
- Enables formulation of water-insoluble APIs in all dosage forms
- Lower API doses can be achieved

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There are 11 APIs on the market and at least 60 further in development in formulations containing SBECD including:

- Voriconazole
- Carfilzomib
- Amiodarone
- Ziprasidone
- Maropitant (veterinary use)
- Aripiprazole
- Posaconazole
- Carbamazepine
- Melphalan
- Delafloxacin
- Brexanolone
- Mebendazol
- Topiramate
- Omeprazole
- Clopidogrel
- Docetaxel
- Meloxicam
- Allopregnanolone
- Iohexol

Several other nitrogen containing API bases are in various clinical phases

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Main regulatory/QA/sales aspects:

- **Maintained DMF Type IV** for SBECD in US and Canada since 2008, in China since 2019

- Prepared via a self-developed **proprietary, patented technology** with a process **independent from any existing patents (expires in 2031)**

- **36-month stability** data (60-month by July, 2021)

- Successful production of over 200 subsequent USP compliant batches – **no OOS result in the production**

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for Improved Pharmaceutical Formulations

Main regulatory/QA/sales aspects:

- Dedicated production facility with a capacity of over **15000 kg/year** (extendable to 20-30,000 kgs/yr without investment)

- **110-125 kg batch size**

- Quality system compliant to **ISO 9001 and GMP** requirements (regularly audited)

No down payment, No milestone payment, No royalty payment

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Main regulatory/QA/sales aspects:

- Over 60 APIs in development using Dexolve

- **Over 200 partners in commercial and development phases using Dexolve**

- **Research grade material available at reduced price for non-clinical development**

- Flexible business model to handle partners' requests and **provide technical support** on development

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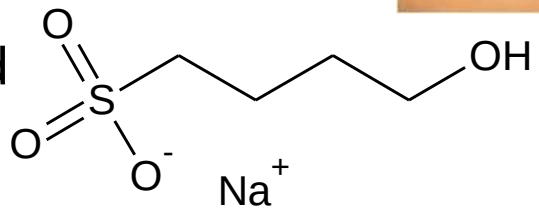
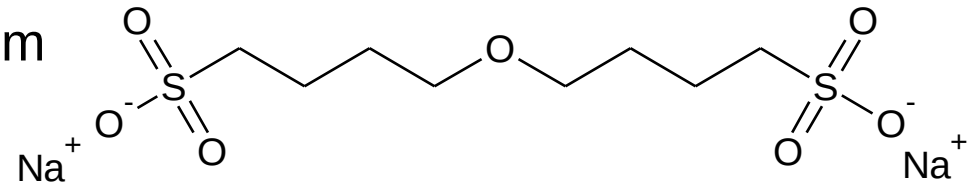
Available reference materials:

- Betadex

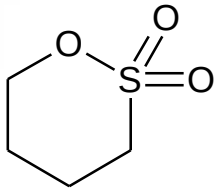
- 4-Hydroxybutane-1-sulfonic Acid



- Bis(4-sulfobutyl) Ether Disodium



- 1,4-Butane Sultone



- Betadex Sulfobutyl Ether Sodium

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Company contacts – ASK FOR A FREE SAMPLE:

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User's guide for Dexolve

A simple 3-step manual for successful dissolution of your drug substance

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STEP 1

Weigh in the following Dexolve amounts into 20 ml vials and prepare solutions with the given volume of distilled water:

Dexolve-7*	Distilled water
3.0 g	7.0 mL
2.0 g	8.0 mL
1.0 g	9.0 mL
0.5 g	9.5 mL

**for accurate results take the water content of Dexolve into consideration*

Use stirrer bar and magnetic stirrer.

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STEP 2

- After the complete dissolution of Dexolve, add ~50 mg or appropriate volume of your drug (candidate) to each vial. Should you be short of material, take smaller volume of the Dexolve solutions and dispense reduced amount of your substance, accordingly.

- Stir the resulting suspensions for 24 hours at room temperature. If your substance is sensitive, then cool your samples and protect them from light in the meantime.

- Observe the vials. If your substance completely dissolves upon stirring, dispense additional amount of your substance. Always ensure excess of material to be dissolved.

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STEP 3

- When finished, filter the suspensions through PVDF syringe filters.

- Analyze the filtrate for your drug content.

- Establish relationship between the concentrations of Dexolve and the solubilized amounts of drug substance. Compare the data with the pure aqueous solubility of your substance.

In case you need technical help to facilitate the dissolution or to improve the solubilizing potency further,

contact us!