

# USER'S GUIDE FOR DEXOLVE™

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

Dexolve™ is the EP/USP compliant SBECD of Cyclolab Ltd.



#### DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



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

Dexo	lve ™*	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



<sup>\*</sup>for accurate results take the water content of Dexolve™ into consideration

#### DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



- After the complete dissolution of Dexolve<sup>™</sup>, 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<sup>™</sup> 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.



### DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



- 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!



### Why use Dexolve™?



- 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



## APIs on the market or in development in formulations containing SBECD



- Voriconazole
- Carfilzomib
- Amiodarone
- Ziprasidone
- Maropitant (veterinary use)
- Posaconazole

- Carbamazepine
- Melphalan
- Topiramate
- Aripiprazole
- Clopidogrel
- Docetaxel

Several other nitrogen containing API bases are in various clinical phases.



## DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS

#### **COMPANY CONTACTS**

## CYCLOLAB CYCLODEXTRIN RESEARCH & DEVELOPMENT LABORATORY LTD.

Budapest, P.O. Box 435, H-1525 Hungary

**Location:** Illatos út 7., Budapest, H-1097- Hungary

**Tel:** (+36) 1-347-60-70

E-mail: dexolve@cyclolab.hu

Web: http://www.cyclolab.hu

#### **CONTACT PERSON**

ASK FOR A FREE SAMPLE

#### **Zoltán Kovács**

Senior Business Development Specialist

kovacs@cyclolab.hu

(+36) 30-163-71-77

