

CYCLOLAB



The Cyclodextrin Company



User's guide for Dexolve™

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

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:

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1**

| Dexolve™* | 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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- 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.

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2**

- 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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S T E P 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!***



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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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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