



# GETTING THE BEST OUT OF CYCLODEXTRINS

**CycloLab's  
Betadex Sulfobutyl Ether  
Sodium  
(Dexolve™)**



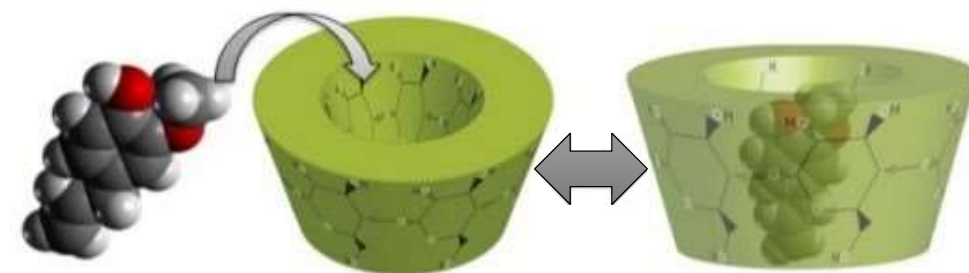


**DEXOLVE**

**CycloLab's USP and EP compliant SBECD**

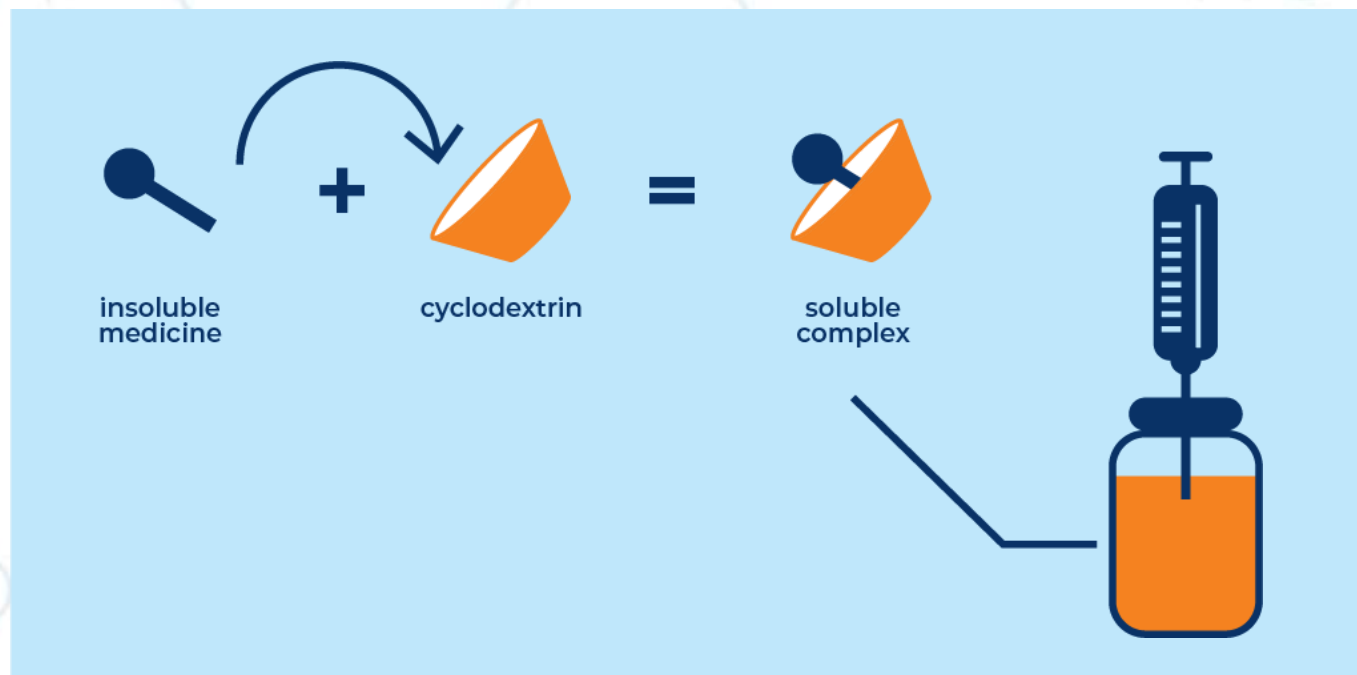
# WHAT ARE CYCLODEXTRINS?

- Composed of sugars
- Cyclic molecules
- Naturally occurring compounds
- Used in food, pharmaceuticals, drug delivery, chemical industries, agriculture, etc.
- **Sub-nanometer** sized molecular containers with hydrophilic outer phase and hydrophobic interior properties
- Reversible inclusion complex formation



## MAIN FUNCTIONAL PROPERTIES OF CDs

They form **NON-COVALENT** „host-guest” type inclusion complexes in a **reversible** manner (Szejtli,1980)



**Cyclodextrins may increase**



- Drug solubility
- Wetting, dissolution rate
- Drug stability
- Absorbed quantity

**Cyclodextrins may decrease**



- API's dose for same efficacy
- Taste
- Side effects
- Smell

## CDs USED IN PHARMACEUTICALS

>100 pharma products on the market containing cyclodextrins



	$\alpha$ -CD	$\beta$ -CD	$\gamma$ -CD	HP- $\beta$ -CD	SBE- $\beta$ -CD	RM- $\beta$ -CD	HP- $\gamma$ -CD
<u>ORAL</u>		X	X	X	X		
NASAL						X	
RECTAL		X		X			
DERMAL		X	X	X			
<u>OCULAR</u>		X		X	X	X	X
<u>PARENTERAL</u>	X			X	X		X

European Medicinal Agency EMA/CHMP/333892/2013, Committee for Human Medicinal Products (CHMP)  
Background review for cyclodextrins used as excipients

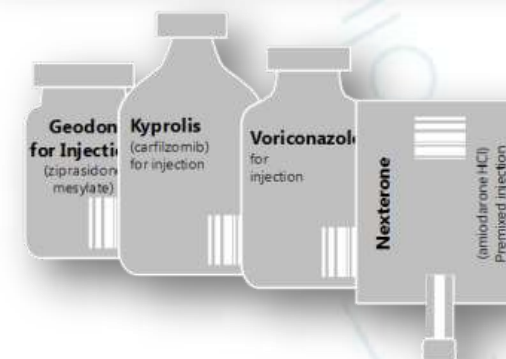
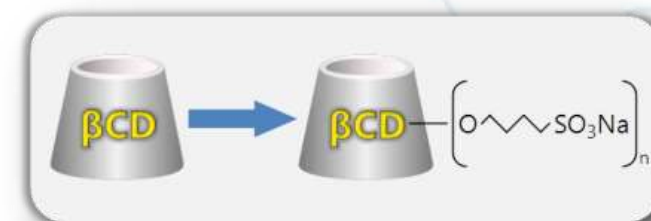


## DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



CycloLab Ltd. is the producer of the **first generic USP and EP-conform Betadex Sulfobutyl Ether Sodium (SBECD = 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



# DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



	Solubility increase using 10 m/m % SBECD vs purified water
<b>Piroxicam</b>	<b>20X</b>
<b>Carbamazepine</b>	<b>36X</b>
<b>Amiodarone</b>	<b>50X</b>
<b>Voriconazole</b>	<b>85X</b>
<b>Delafloxacin</b>	<b>340X</b>
<b>Ziprasidone* HCl</b>	<b>470X</b>
<b>Aripiprazole</b>	<b>3350X</b>
<b>Posaconazole pH 6</b>	<b>20X</b>
<b>Posaconazole pH 3</b>	<b>120X</b>

Aqueous solubilities: Pubmed database (<https://pubchem.ncbi.nlm.nih.gov>)  
solubility in SBECD solutions: CycloLab results



DMF No.  
21922



OGYÉI/577  
92-7/2018



DMF No.  
2009-080



DMF No.  
F20180001741



202107558



OGYÉI/3039  
1-2/2018



## DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



There are 17 APIs on the market and at least 150 further in development in formulations containing SBECD including

- Voriconazole (Vfend, Pfizer)
- Carfilzomib (Kyprolis, Amgen)
- Amiodarone (Nexterone, Baxter)
- Ziprasidone (Geodon, Pfizer)
- Maropitant (vet., Cerenia, Zoetis)
- Aripiprazole (Abilify, BMS)
- Posaconazole (Noxafil, MSD)
- Carbamazepine (Carnexiv, Lundbeck)
- Melphalan (Evomela, Spectrum)
- Delafloxacin (Baxdela, Melinta)
- Brexanolone (Zulresso, Sage)
- Remdesivir (Veklury, Gilead)
- Fosphenytoin (Sesquent, Sedor)
- Alfaxalone (Phaxan, Drawbridge)
- Docetaxel (Docetaxel inj., Meridian)
- Levothyroxine (Levothyroxine inj., Laucadia)
- Posaconazole (Noxafil, Merck)

- Mebendazol
- Topiramate
- Omeprazole
- Clopidogrel
- Meloxicam
- Allopregnanolone
- Iohexol
- Busulfan
- Alphaxalone

Several other nitrogen containing APIs are in various clinical phases





Main regulatory / QA / sales aspects:

**Maintained DMF Type IV** for SBECD in US and Canada since 2008, in China since 2019, in Korea since 2021.

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

60-month stability data

Successful production of over 250 subsequent USP compliant batches - **no OOS result in the production**

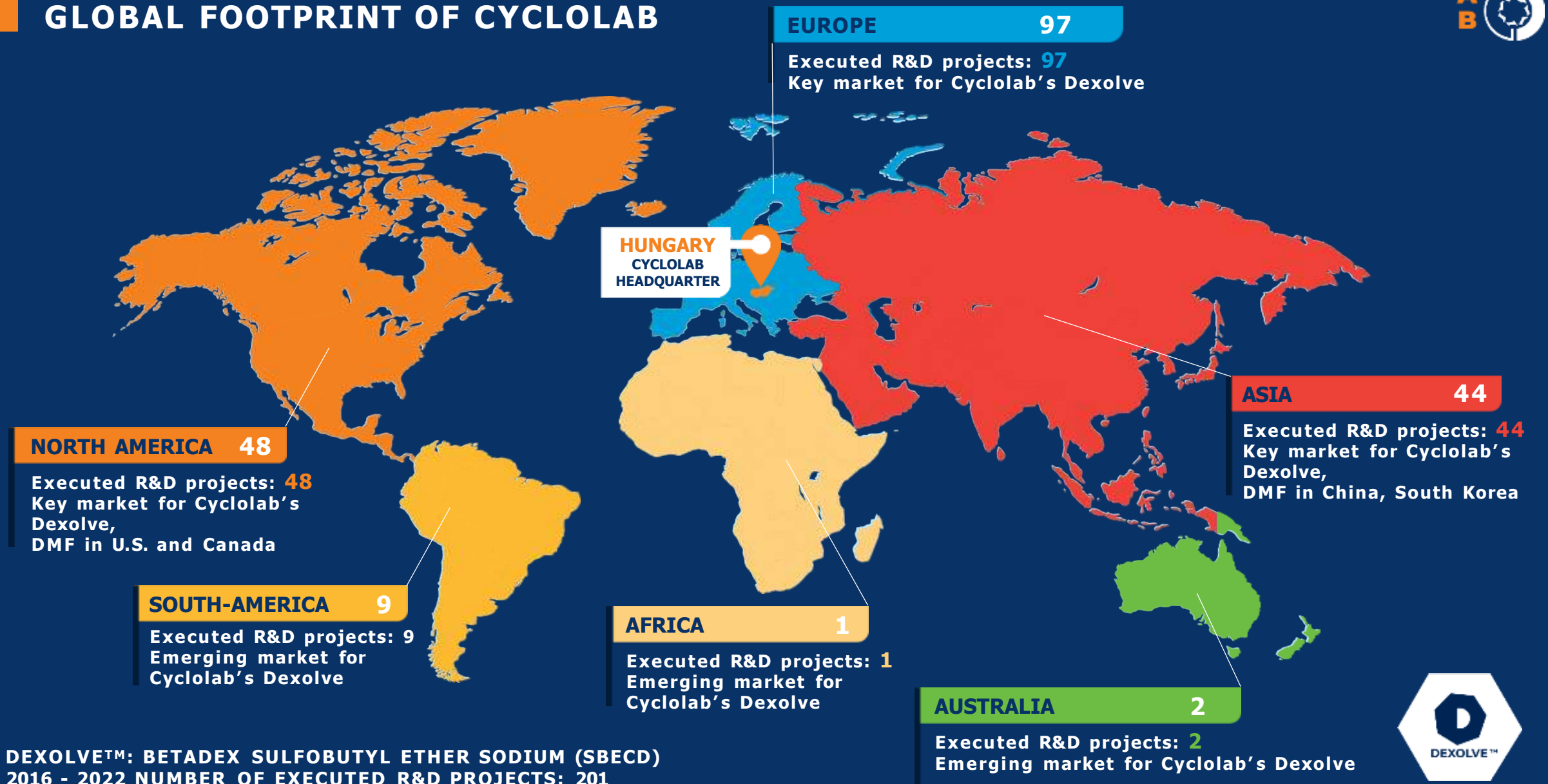
**Dedicated production facility, with 30000+ kg annual capacity** producing up to **360+ kg batches**

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

**~100 APIs of over 500 partners in development using Dexolve in commercial and development phases**

**Flexible business model, technical and regulatory support on development**

# GLOBAL FOOTPRINT OF CYCLOLAB



## COMPANY CONTACTS

### **CYCLOLAB CYCLODEXTRIN RESEARCH & DEVELOPMENT LABORATORY LTD.**

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

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

**Web:** <http://www.cyclolab.hu>

## CONTACT PERSON

**Bohdan TI TULA**

*Managing Director*

E-mail:

[bohdan.titulac@cyclolab.hu](mailto:bohdan.titulac@cyclolab.hu)

**Sales department**

E-mail: [commerce@cyclolab.hu](mailto:commerce@cyclolab.hu)

