



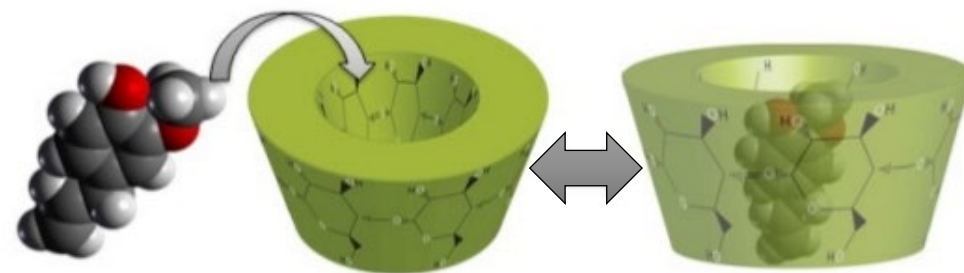


## DEXOLVE

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

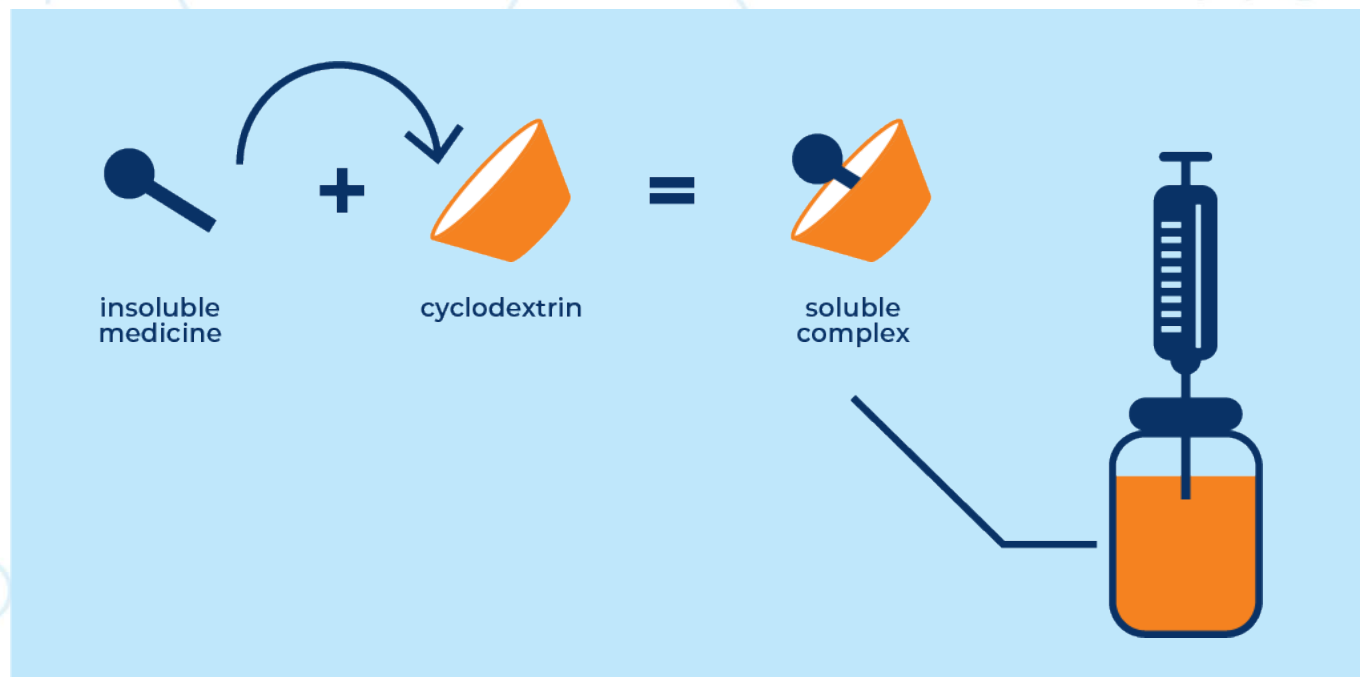
# WHAT ARE CYCLODEXTRINS?

- 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

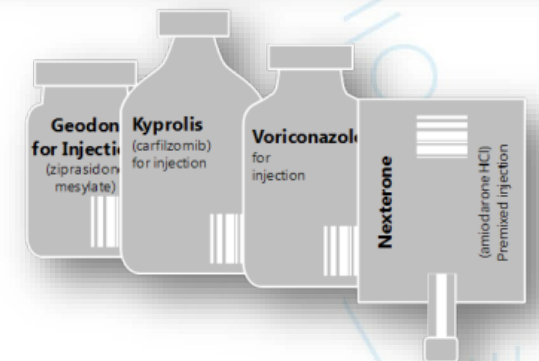
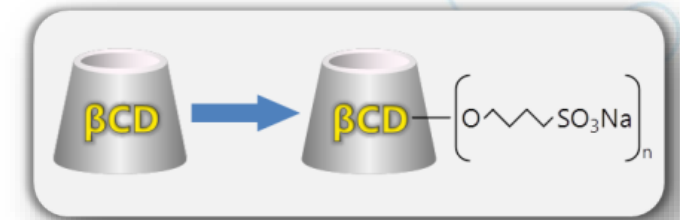


# DEXOLVE™ FOR IMPROVED PHARMACEUTICAL FORMULATIONS



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



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



DMF No.  
21922



OGYÉI/577  
92-7/2018



DMF No.  
2009-080



DMF No.  
F20180001741



202107558

**EudraGMDP**

OGYÉI/3039  
1-2/2018

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



There are **13 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 (Sesquient, Sedor)

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

Several other nitrogen containing APIs are in various clinical phases



**DEXOLVE™**  
**FOR IMPROVED PHARMACEUTICAL FORMULATIONS**



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 (expires in 2031)** with a process **independent from any existing patents**

59-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 **720+ kg batches**

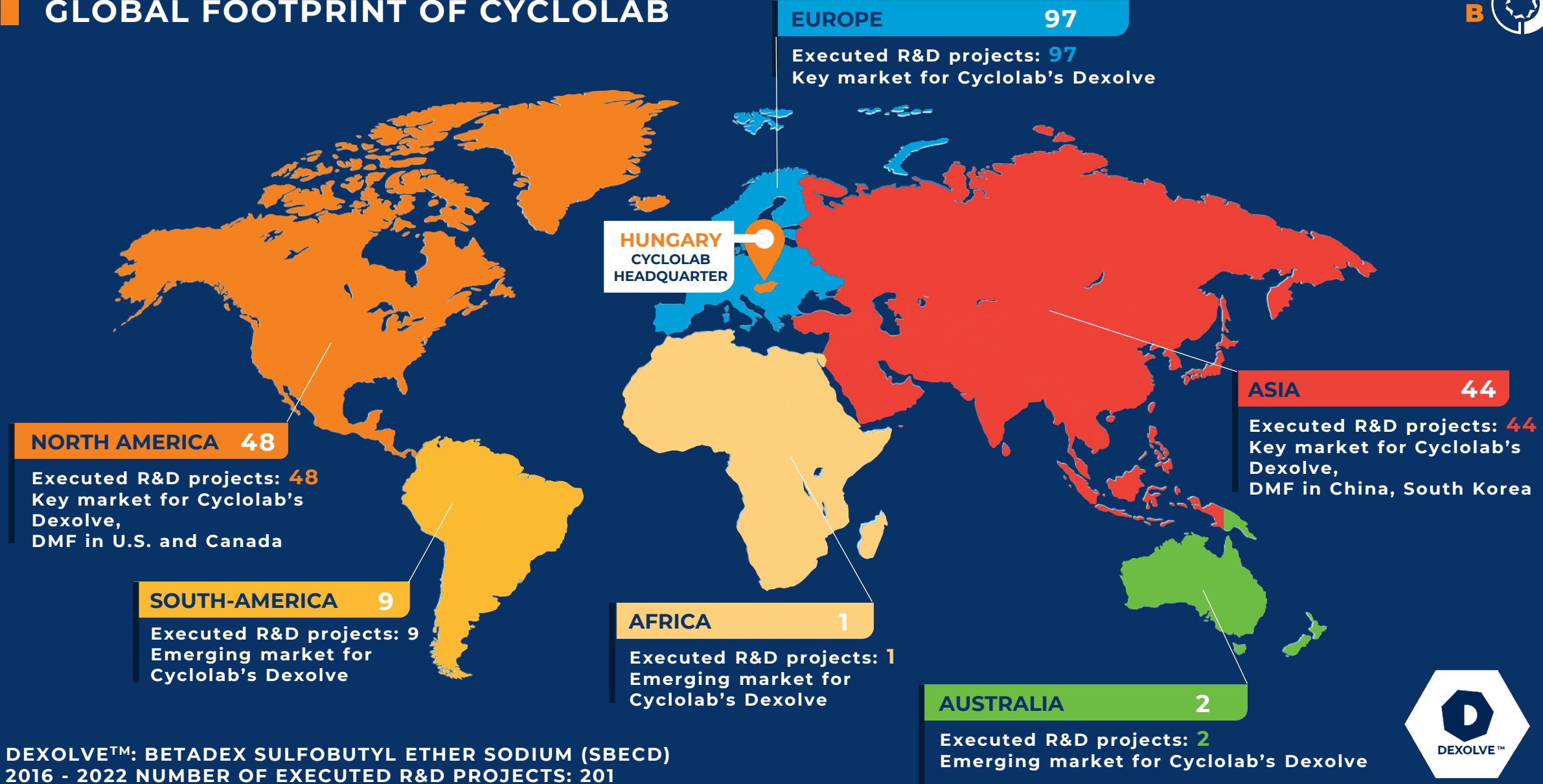
Quality system compliant to **ISO 9001 and GMP** requirements (regularly audited)

Over 82 APIs of over **400 partners** in development using Dexolve in commercial and development phases

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



# GLOBAL FOOTPRINT OF CYCLOLAB



**DEXOLVE™: BETADEx SULFOBUTYL ETHER SODIUM (SBECD)**  
2016 - 2022 NUMBER OF EXECUTED R&D PROJECTS: 201



**DEXOLVE™**  
**FOR IMPROVED PHARMACEUTICAL FORMULATIONS**

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