

GETTING THE BEST OUT OF CYCLODEXTRINS

Analytical services by CycloLab



Who are we at CycloLab?



The world's only all-round **CYCLODEXTRIN** company with over **40-year experience of CD-technology**

CycloLab started as a spin-off of Sanofi-Aventis Chinoin Pharma (1990)

Over 40-year experience in all fields of CD-technology

- **Based in Budapest, Hungary**
- **500 m2 dedicated analytical laboratories**
- **qualified analysts (8 Ph. D.)**
- **Modern instrumentation (not older than 5 years)**
- **100+ year of cumulative experience in analyzing cyclodextrins and cyclodextrin-based formulations**



The CycloLab analytical testing laboratories offer a diverse range of analytical techniques and hundreds of different tests.

CycloLab helps clients solve quality issues, support research projects, troubleshoot, mitigate risk and much more. Our laboratories test a wide range of chemicals and materials, working with clients on a global basis.

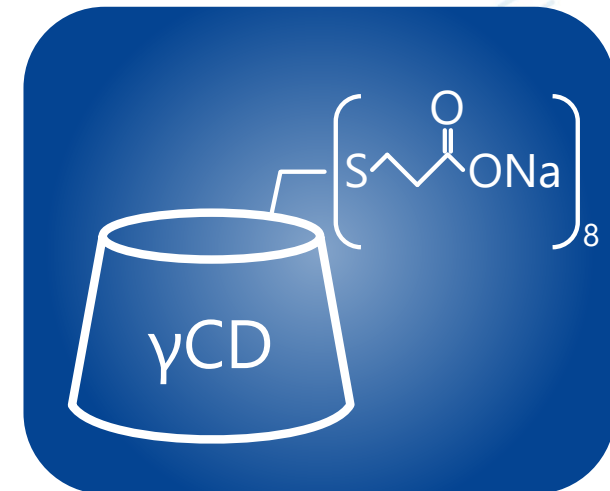
Vast experience in the field of cyclodextrins (CDs): to characterize cyclodextrins, cyclodextrin complexes, to perform related analysis (API assay, formulation specific characterization)

Our experience also includes analysis of cyclodextrins in complex biological matrices like blood plasma or liquor samples

Analytical applications of cyclodextrins (chiral separation, CD-induced fluorescent emission, etc.)

High performance liquid chromatography (HPLC): DAD, ELSD, CAD, RI, MS detectors

- Determination of impurities, purity, identification, assay in cyclodextrin samples
- Qualitative and quantitative determination of material (cyclodextrin or API) in formulations
- CD content in biological samples or in drug formulations
- Forced degradation (stress) studies
- Analysis of Sugammadex samples



Gas chromatography (GC)

- Determination of volatile organic components, residual solvents, volatile active ingredient content in cyclodextrin complexes
- Assessment of interaction strength of volatile guests with CDs

Capillary electrophoresis (CE)

- Determination of interaction strength between API and cyclodextrins
- Residual ionic compounds
- Average degree of substitutions of charged cyclodextrins
- Chiral separations

CycloLab's analytical portfolio

Spectroscopic and spectrometric methods



Nuclear magnetic resonance spectroscopy (NMR)

- Structure identification
- Determination of interaction strength between API and cyclodextrins
- Assessment of stoichiometry and complex structure

Matrix Assisted Laser Desorption Ionization - Time of Flight-Mass spectrometry (MALDI-TOF-MS)

- Molecular weight determination of CD derivatives including polymers
- Distribution of the degree of substitutions

Electron Spray Ionization - Mass spectrometry (ESI-MS)

- Identification of novel CD derivatives



CycloLab's analytical portfolio



- ICH stability testing
- Elemental impurities by ICP-MS
- Microbial testing: TAMC, TYMC, bacterial endotoxins, E. coli, Salmonella, Pseudomonas A., Staphylococcus A, etc.
- Isothermal titration calorimetry: determination of interaction strength and complex stoichiometry
- Powder analysis: Differential scanning calorimetry, X-Ray powder diffraction, Scanning electron microscopy, Transmission electron microscopy, Laser diffraction analysis, Raman mapping, Scanning Electronmicroscopy with X-ray microanalysis, Tapped density, Bulk density



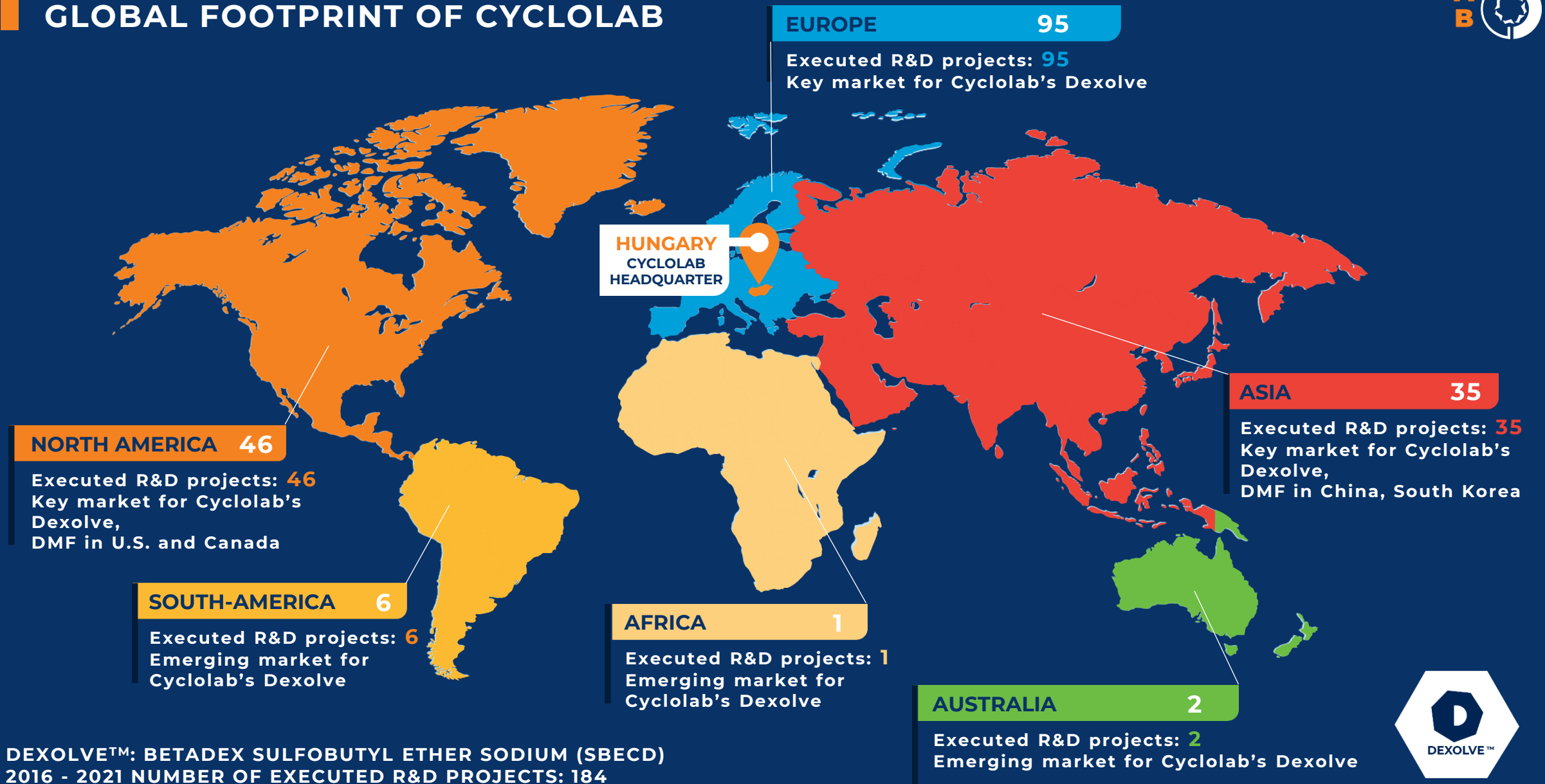
CycloLab's analytical portfolio



- Bioequivalence studies: membrane permeation, protein binding, dissolution and dilution studies for formulation samples
- Surface tension measurement, viscosity determination, refractive index for solution
- Circular dichroism
- Classical analytical measurements: pH, osmolality, wet chemistry, conductometry, UV/VIS
- Water content determination: Karl-Fischer titration and loss on drying



GLOBAL FOOTPRINT OF CYCLOLAB



DEXOLVE™: BETADEx SULFOBUTYL ETHER SODIUM (SBECD)
2016 - 2021 NUMBER OF EXECUTED R&D PROJECTS: 184



Summary

- The applied techniques include traditional analytical techniques: HPLC, GC, ESI-MS, MALDI-TOF-MS, NMR, IR, CE, Dynamic and Static Light Scattering
- Complete analysis of CD derivatives according to the current pharmacopeial monographs
- Stability and forced degradation studies on CD derivatives and CD complexes
- Method developments for R&D purposes
- Analysis of CDs in drug formulations and in complex biological matrices
- Application of CDs in separation sciences
- CD-enabled chiral separations on analytical and on semi-preparative scale

COMPANY CONTACTS

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