CYCLOLAB

The Cyclodextrin Company

Analytical services by CycloLab

CycloLab Ltd.
Budapest, Hungary

Who are we?

The world's only all-round Cyclodextrin Service Provider

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 m^2 dedicated analytical laboratories**
- **16 qualified analysts (11 Ph. D.)**
- **Modern instrumentation (not older than 5 years)**
- **100+ year of cumulative experience in analyzing cyclodextrins and cyclodextrin-based formulations**

Our services

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, trouble-shoot, 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)

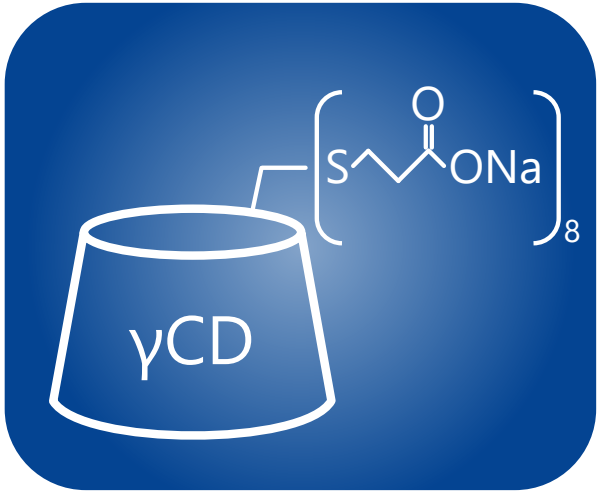
- Our experience also includes analysis of cyclodextrins in complex biological matrices like blood plasma or liquor samples

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

CycloLab's analytical portfolio

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



CycloLab's analytical portfolio

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 subtitutions

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

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**

Analytical services by CycloLab

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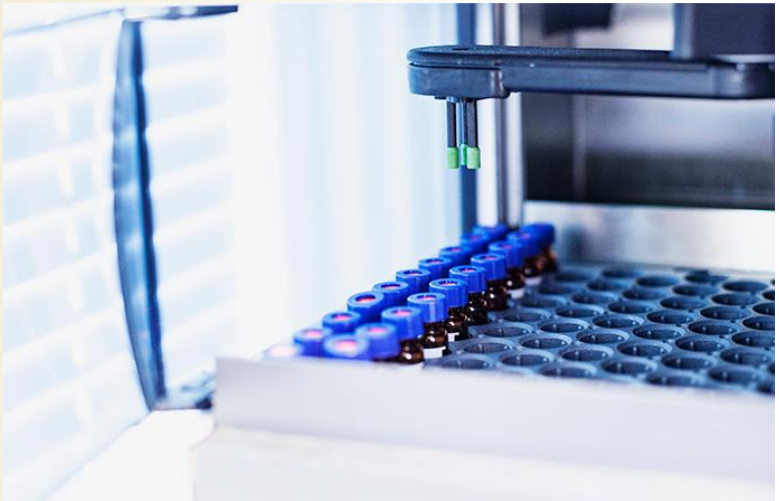

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