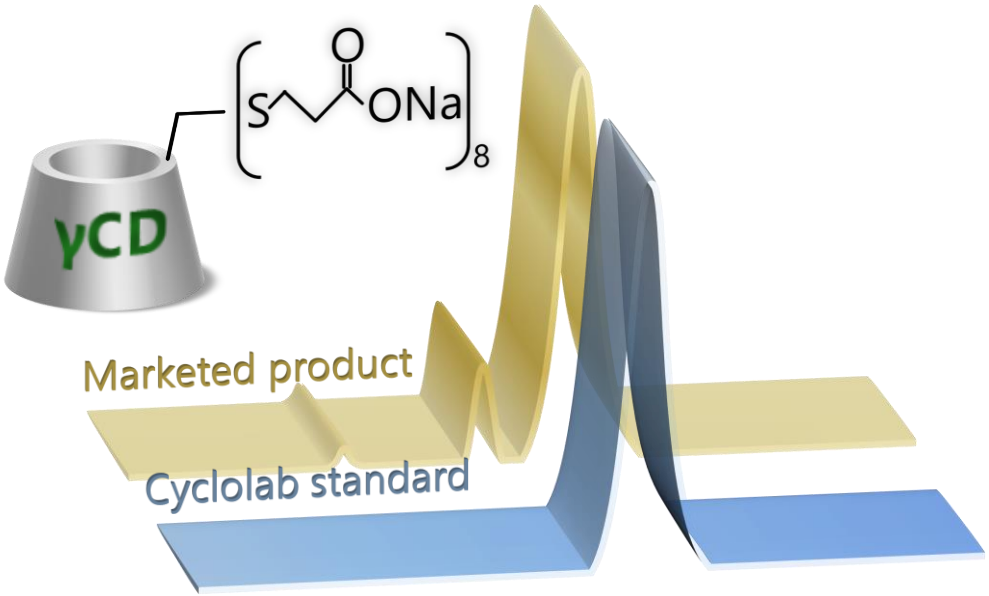
CYCLOLAB

The Cyclodextrin Company

Sugammadex manufacturing technology related process intermediate standards, process impurities and analysis



Sugammadex

Sugammadex is one of the greatest success in the history of cyclodextrins. There is an increasing interest for this product and for the development of Sugammadex since the recent approval by the FDA is estimated to have a 3-4-fold increase in the global sales of the product.

CycloLab has vast experience in the production of Per-6-halogen-gamma-CD intermediates and have performed developed Sugammadex via various process routes and related compounds, supported by sensitive analytical tools to characterize the products.

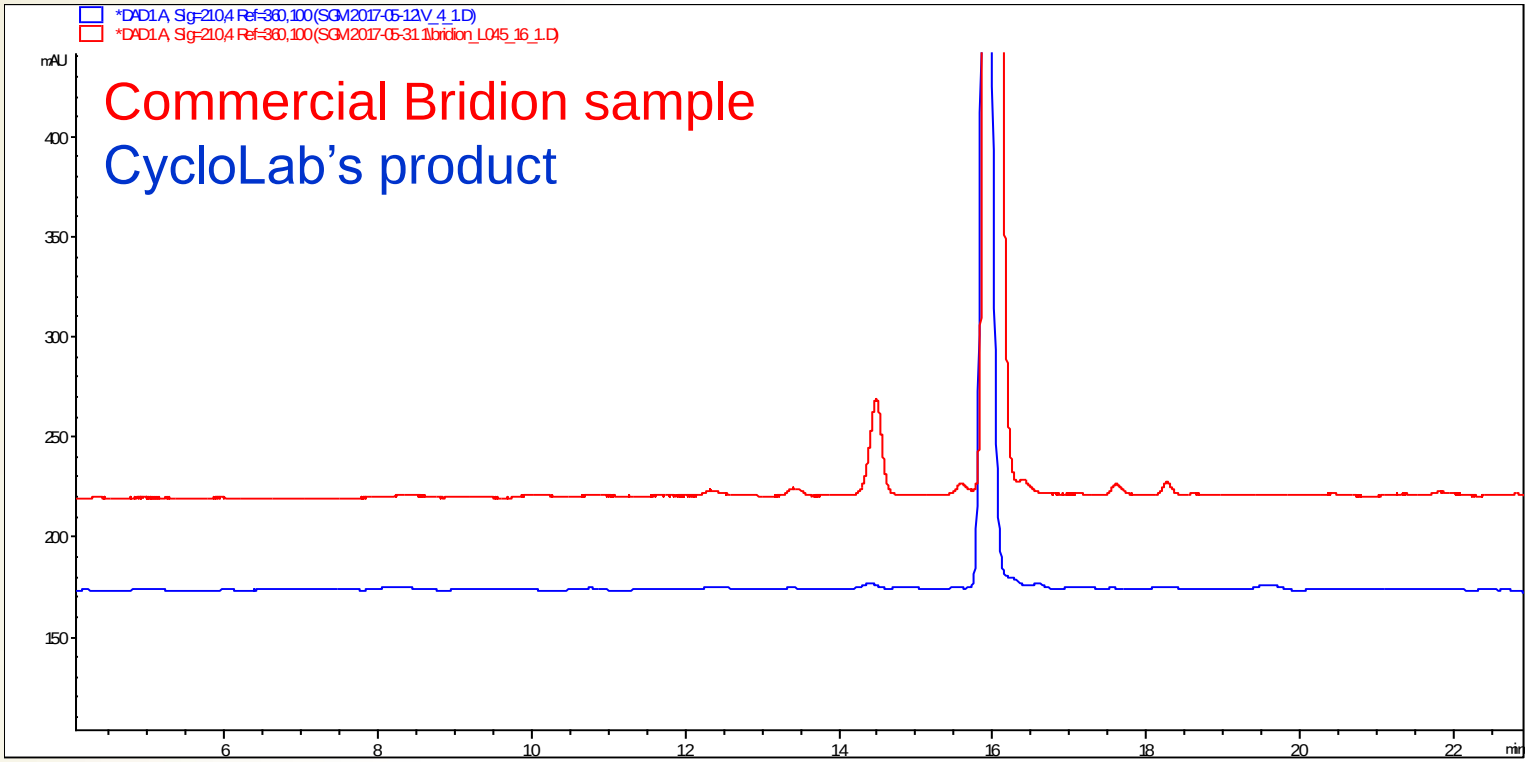
What does CycloLab offer?

- Supplying the key intermediates (Per-6-halogen-gamma-CDs) for the synthesis of the API (on commercial scale)
- Assisting in the optimization of the API production
- Comparing samples (both API and final formulations) using our proprietary sensitive analytical methods (capable of separating 20-30 potential impurities in the API)
- Providing high purity standards (intermediates, Sugammadex, key process impurities) to quantify the true and accurate purity of the compounds

Out-licensing: CycloLab has developed a novel, economic and versatile purification process that allows to obtain Sugammadex with the originator's purity without the need of chromatography.

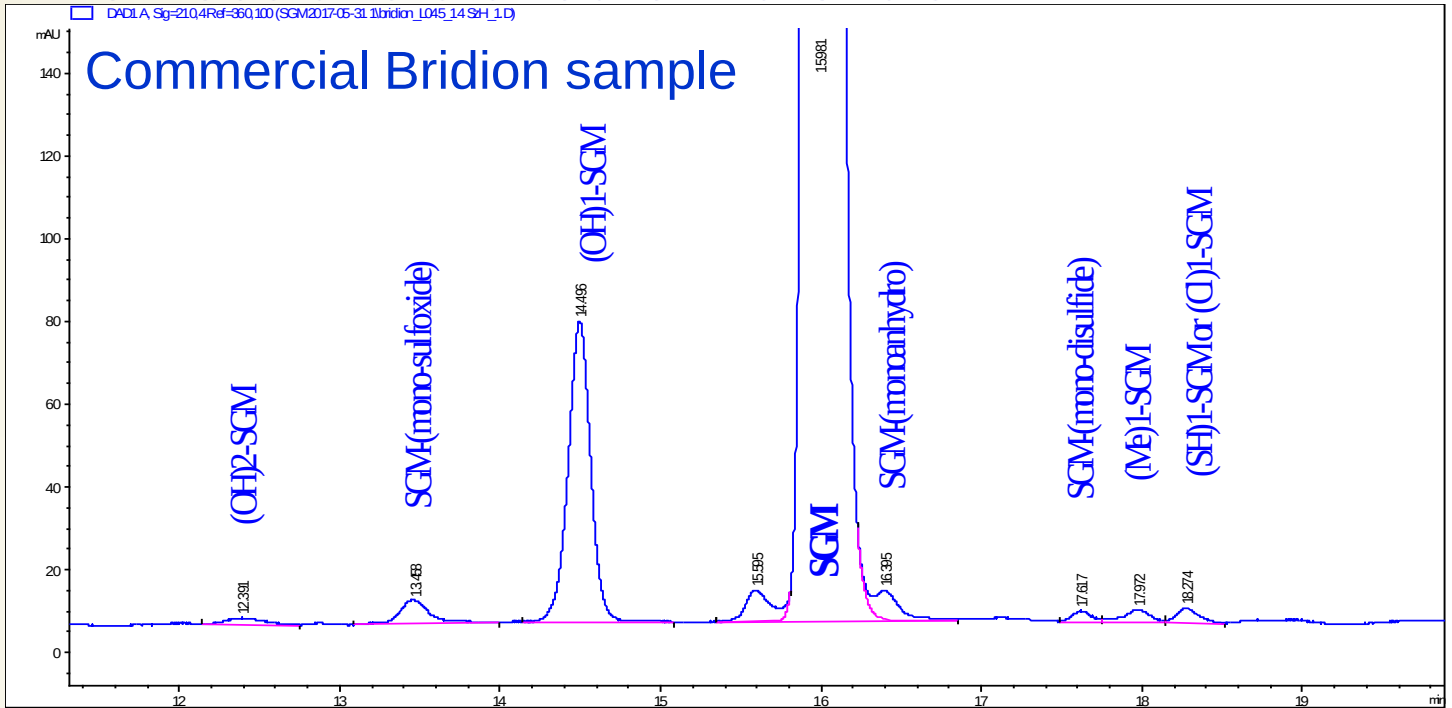
Technology and analysis

Using Cyclolab's proprietary technology, a product quality outperforming the originator's in all aspects can be achieved with an economical production.



Technology and analysis

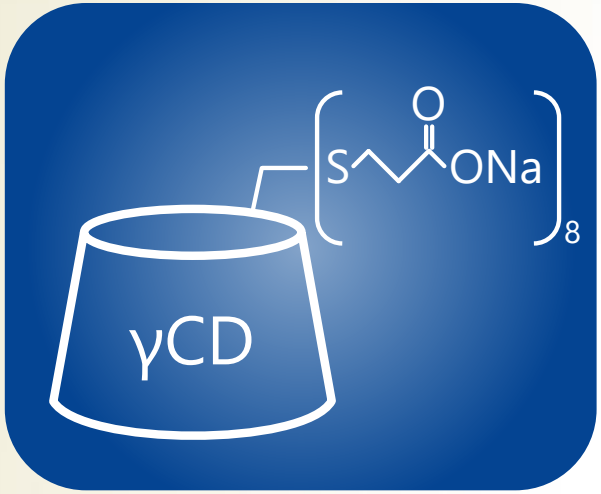
Bridion itself is claimed to potentially contain 14 cyclodextrin related impurities (public regulatory information), while other synthetic approaches generate just as many different ones. The accurate analysis of such an API is not possible without proper methods and standard materials.



Raw material and product standards

Gamma-cyclodextrin Working Standard:

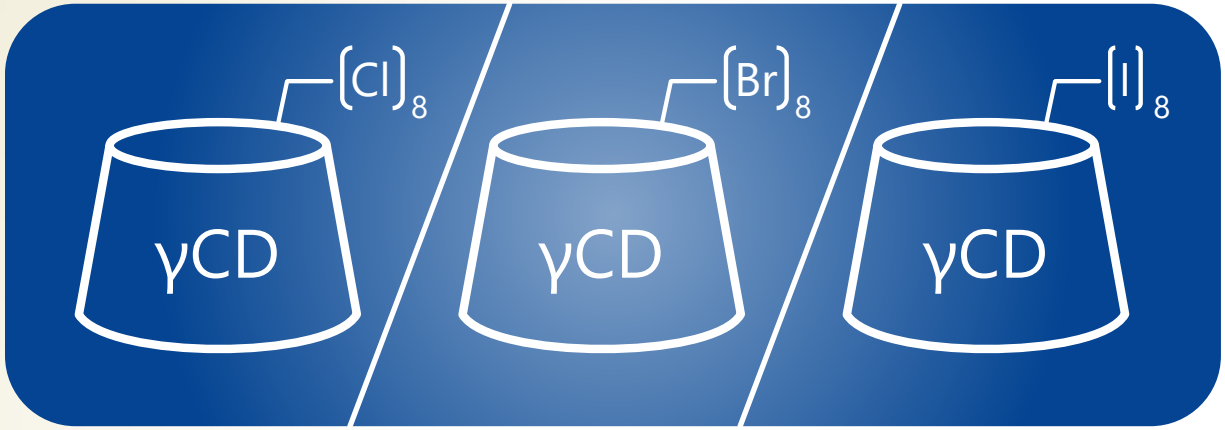
- Declaration by CycloLab



Sugammadex Primary reference standard:

- >99.5% purity (on dry substance)
- Identification by NMR, IR, HPLC and HPLC-MS

Process intermediate standards

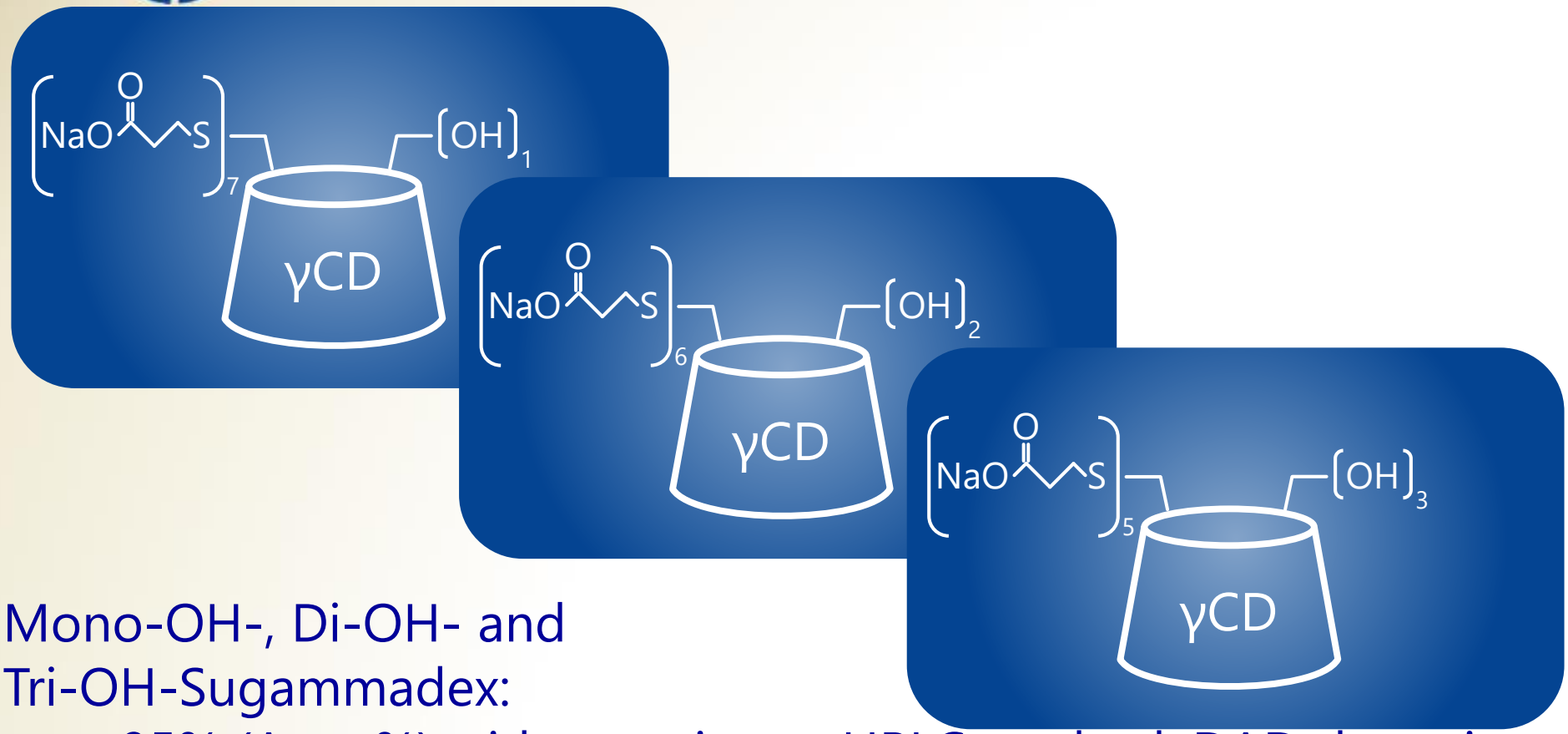


Per-6-halogen-gamma-cyclodextrin primary standards:

- available for any chosen synthetic route (chloro-, bromo- or iodo derivative)
- >90% content
- Identification by NMR, IR

Main impurities (as monoOH-perhalogeno-GCDs) are also available

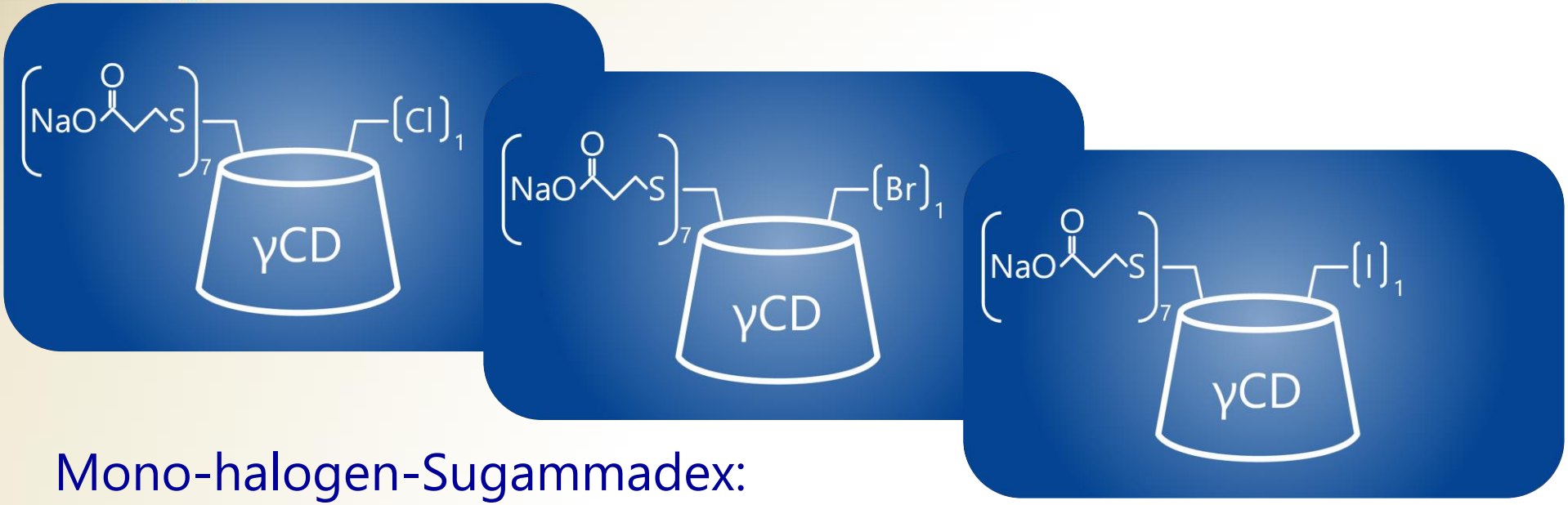
Major process impurities



Mono-OH-, Di-OH- and
Tri-OH-Sugammadex:

- >95% (Area %) with proprietary HPLC method, DAD detection, peak purity proven by LC-MS
- Identification by NMR, IR, HPLC-MS
- Residual solvents by TGM-MS and residual salts by CE

Major process impurities

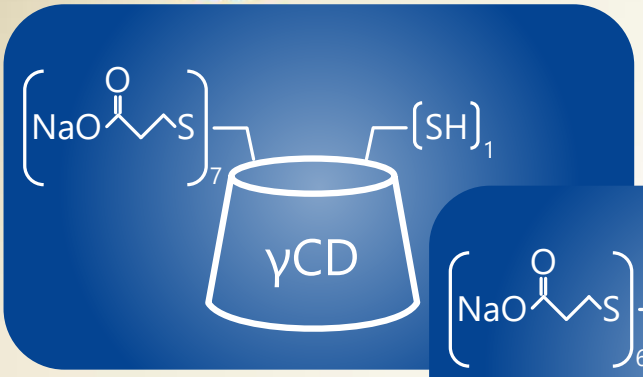


Mono-halogen-Sugammadex:

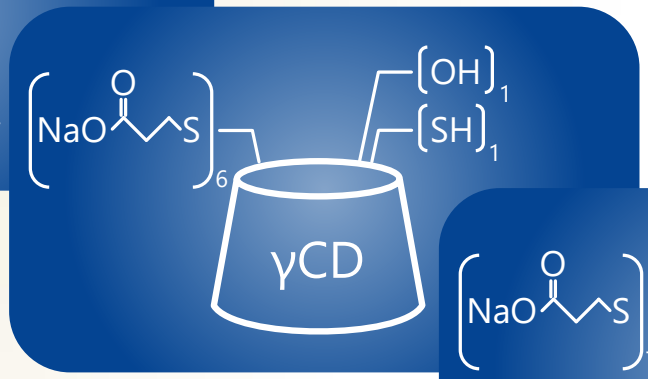
- available for any chosen synthetic route (chloro-, bromo- or iodo derivative)
- >90% (Area %) with proprietary HPLC method, DAD detection, peak purity proven by LC-MS
- Identification by NMR, IR, HPLC-MS
- Residual solvents by TGM-MS and residual salts by CE

Minor process impurities

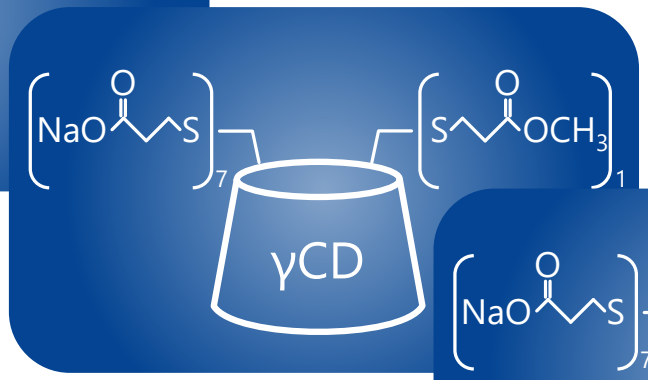
Contact us for any other impurities you identified in your generic Sugammadex!



Mono-thio-Sugammadex



Mono-thio-mono-OH-Sugammadex



Mono-ester-Sugammadex

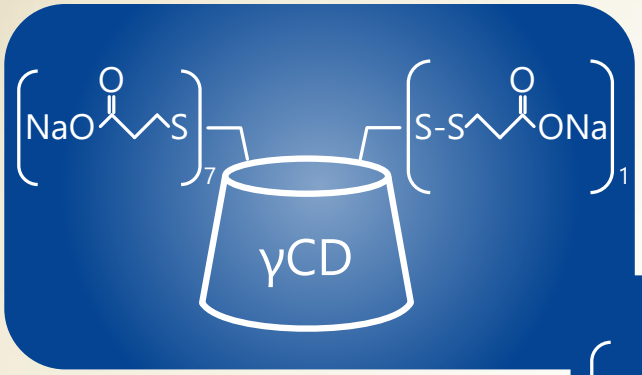
Mono-sulfoxide-Sugammadex

Typical analysis:

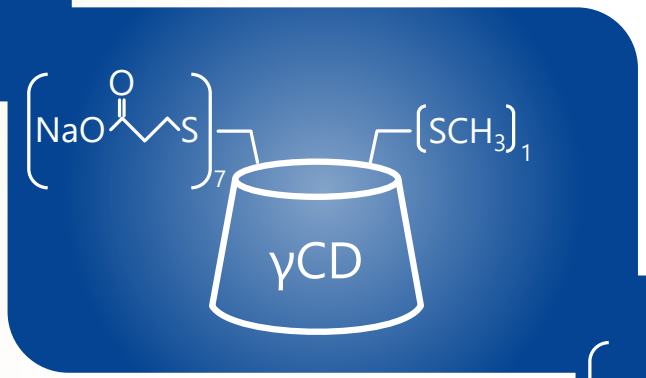
- >90% (Area %) with proprietary HPLC method, DAD detection, peak purity proven by LC-MS
- Identification by NMR, HPLC-MS
- Residual solvents by TGM-MS and residual salts by CE

Minor process impurities

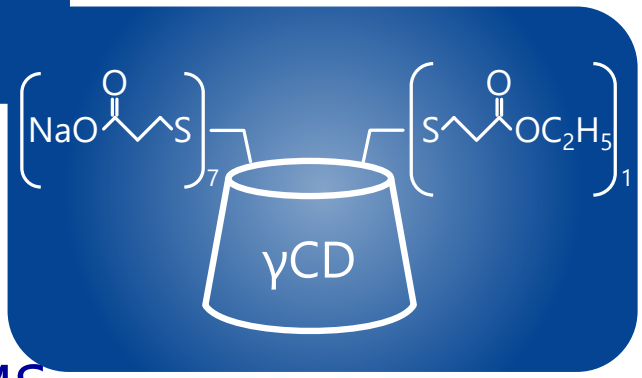
Contact us for any other impurities you identified in your generic Sugammadex!



Mono-disulfide-Sugammadex



Mono-methylthio-Sugammadex



Mono-ester-Sugammadex

Typical analysis:

- >90% (Area %) with proprietary HPLC method, DAD detection, peak purity proven by LC-MS
- Identification by NMR, HPLC-MS
- Residual solvents by TGM-MS and residual salts by CE

Company contacts:

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