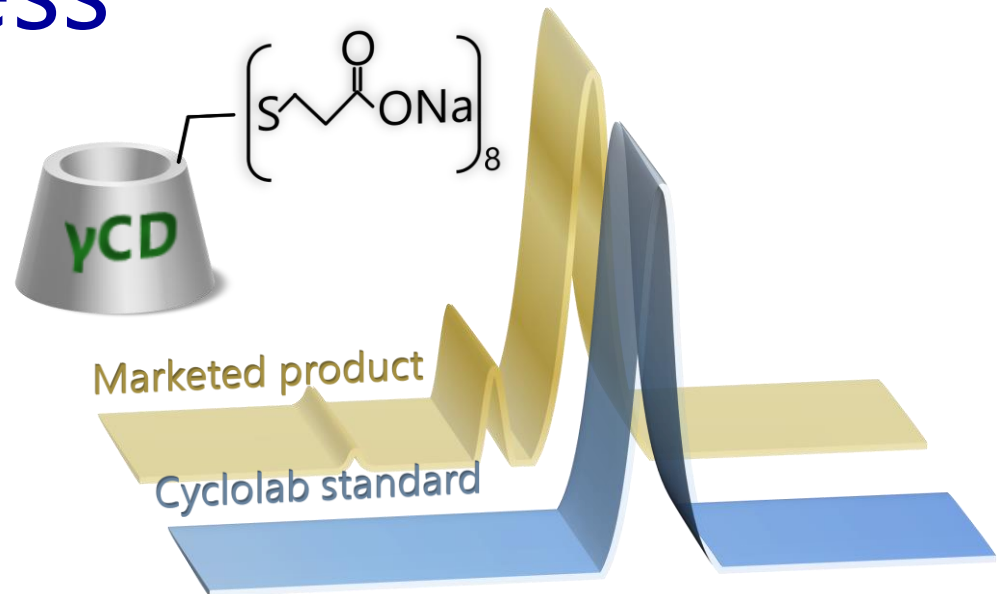




Sugammadex and related process intermediate standards, process impurities





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 several studies to develop Sugammadex 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 and potency of the compounds

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

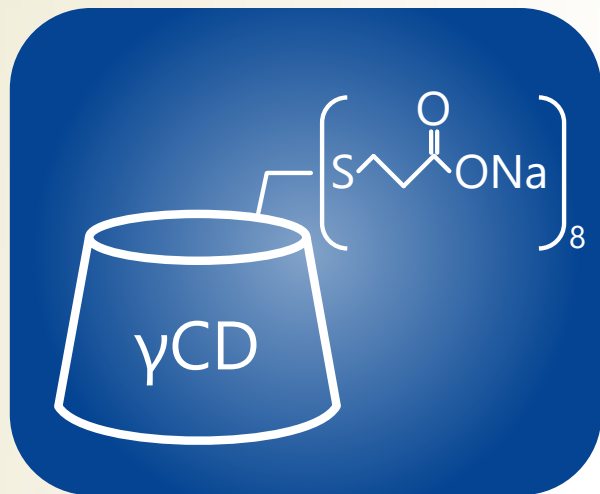


Raw material and product standards



Gamma-cyclodextrin Working Standard:

- Declaration by CycloLab

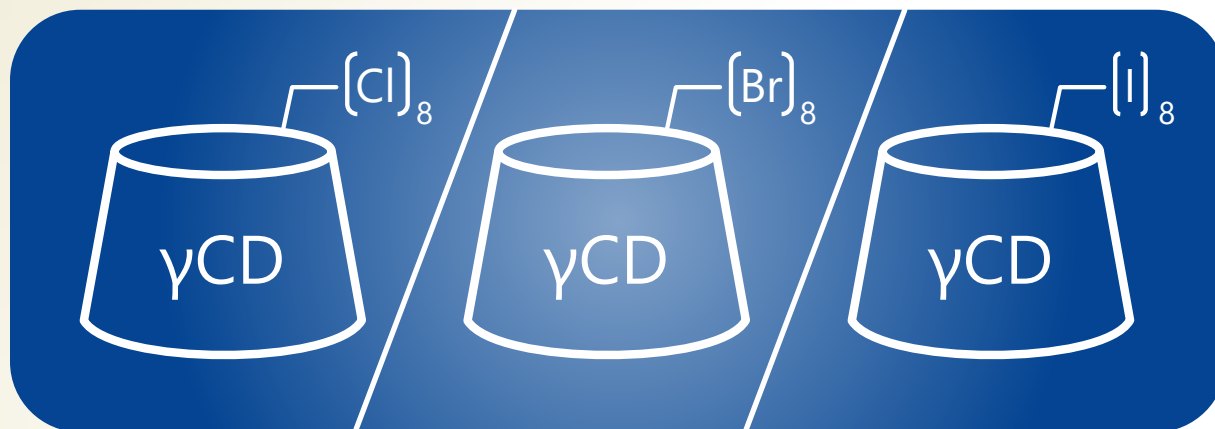


Sugammadex Primary reference standard:

- >98% purity (on dry substance)
- Identification by NMR, IR, HPLC and HPLC-MS



Process intermediate standards

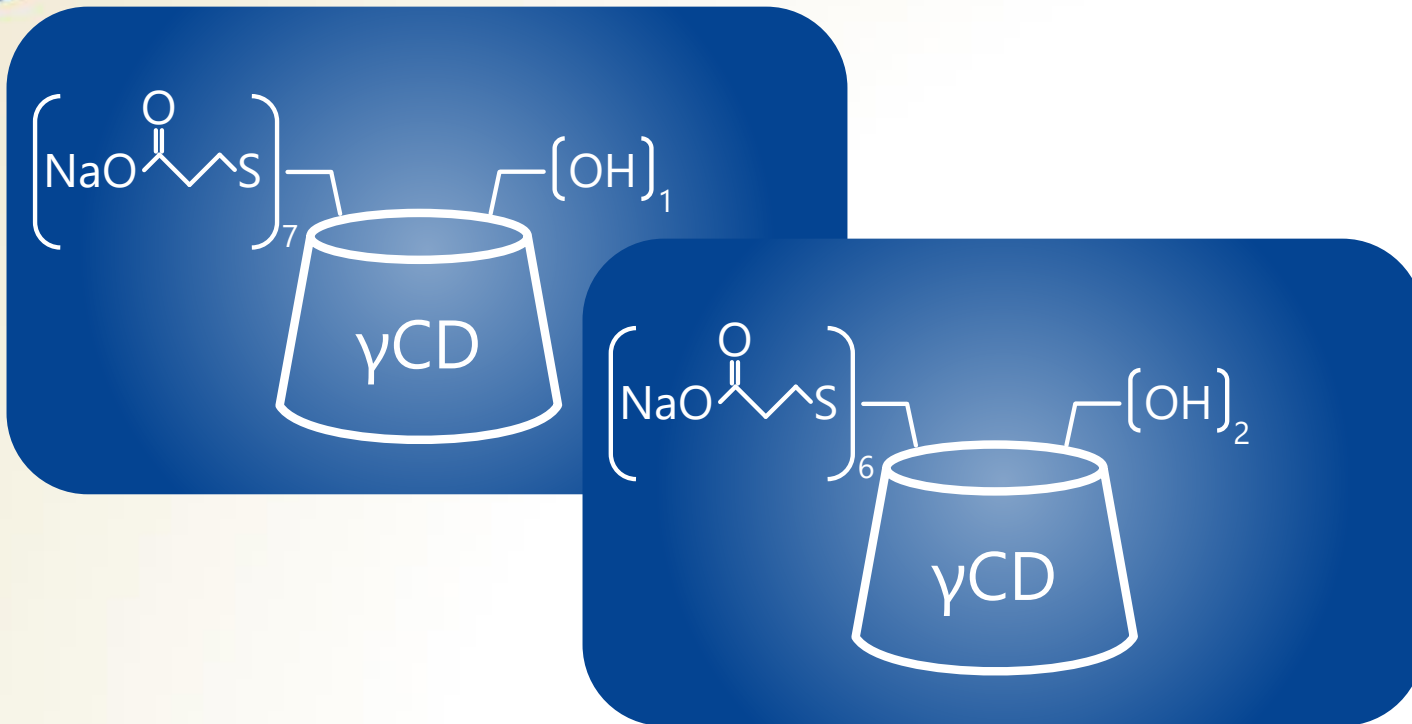


Per-6-halogen-gamma-cyclodextrin primary standards:

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



Major process impurities

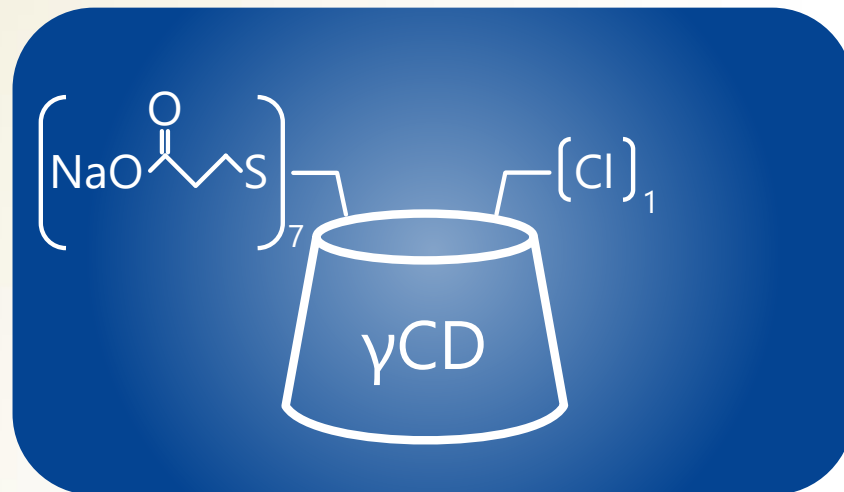


Mono-OH-Sugammadex and Di-OH-Sugammadex:

- >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



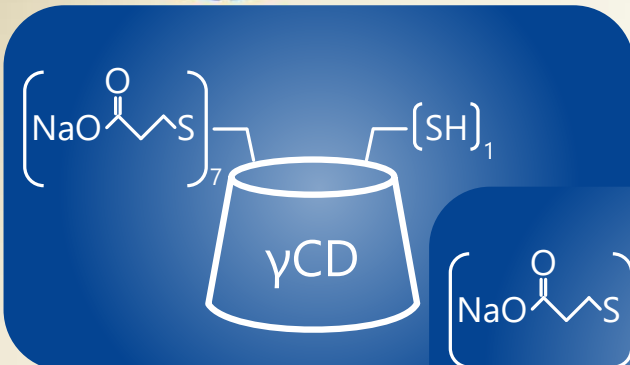
Mono-halogen-Sugammadex:

- 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

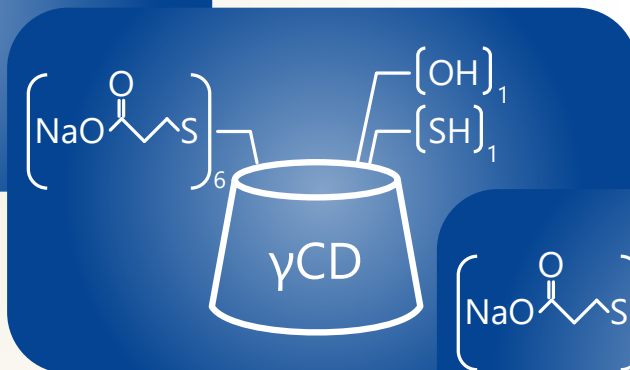


Minor process impurities

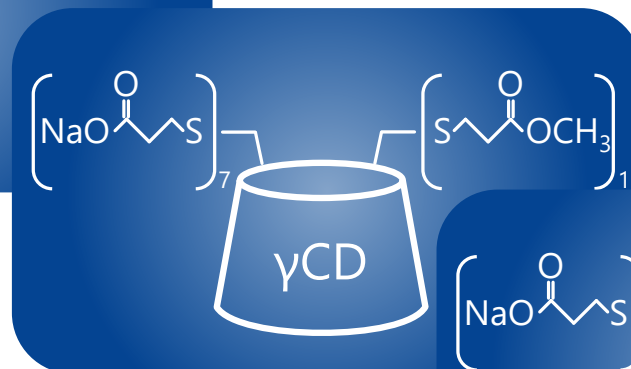
Contact us for any other impurities
you identified in your generic
Sugammadex!



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



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