Sugammadex and related process intermediate standards, process impurities
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.
Gamma-cyclodextrin Working Standard:
• Declaration by CycloLab

Sugammadex Primary reference standard:
• >98% purity (on dry substance)
• Identification by NMR, IR, HPLC and HPLC-MS
Per-6-halogen-gamma-cyclodextrin primary standards:
- available for any chosen synthetic route (chloro-, bromo- or iodo derivative)
- >90% content
- Identification by NMR, IR
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
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

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

Contact us for any other impurities you identified in your generic Sugammadex!
Company contacts:
CycloLab Cyclodextrin Research & Development Laboratory Ltd.
Budapest, P.O. Box 435, H-1525 Hungary
Location: Illatos út 7., Budapest, H-1097 Hungary
Tel: (+36) 1-347-60-60 or -70; Fax: (+36) 1-347-60-68
E-mail: info@cyclolab.hu
Homepage: http://www.cyclolab.hu

Contact person: Zita Vincze
Sales Executive
E-mail: info@cyclolab.hu
Tel: (+36) 1-347-60-62