



# ANALYSIS OF SUGAMMADEX IMPURITIES

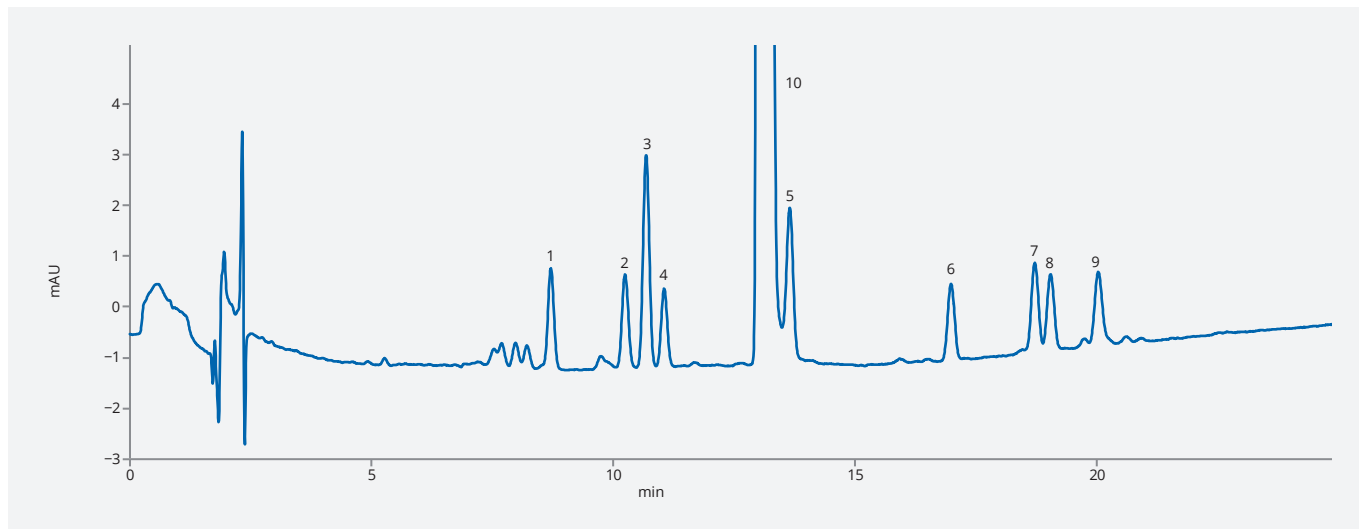
## ABSTRACT

This application describes an analytical approach for the identification of sugammadex impurities, enabling reliable quality control and comprehensive impurity investigations throughout the manufacturing process.

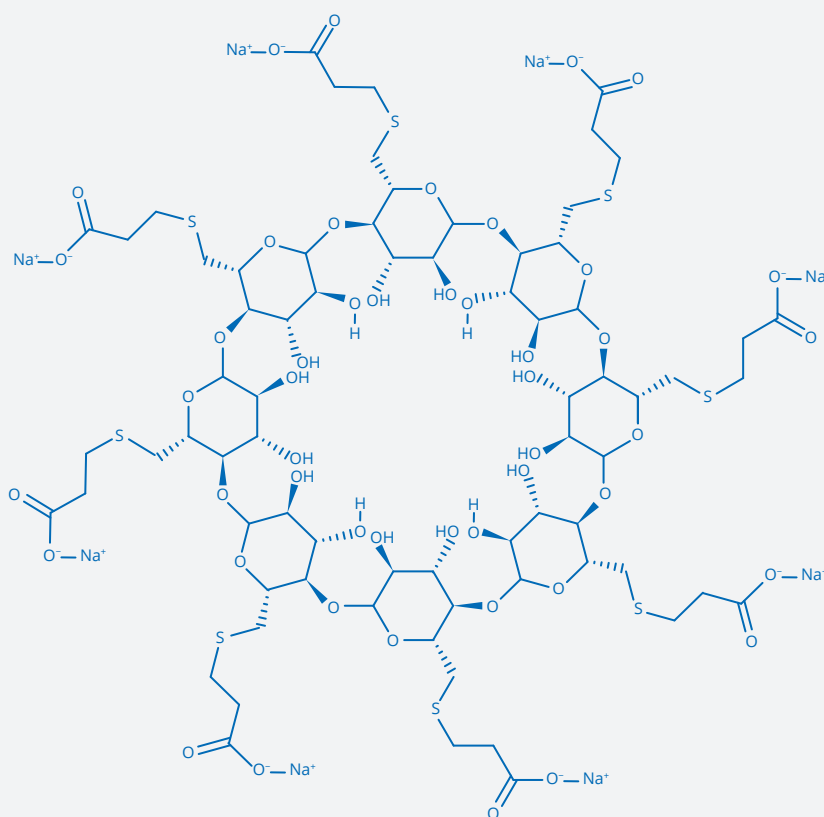
## INTRODUCTION

Sugammadex (SGM) is a modified gamma-cyclodextrin and a selective relaxant-binding agent used in anaesthesia. It blocks the effects of muscle relaxant drugs – rocuronium and vecuronium – by encapsulating them. The development of a sensitive and selective chromatographic method for the detection and separation of SGM impurities is essential for the pharmaceutical industry.

## Analysis of Sugammadex impurities



Chromatogram of SGM sample with impurities (concentration 4 mg/mL for SGM, RT 13.1 min) on Astra® C18-Hybrid column



Sugammadex sodium

## Analysis of Sugammadex impurities

|                         |                                                                                                                                                                                                       |       |       |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|
| <b>Column</b>           | ASTRA® C18-Hybrid, 3 µm                                                                                                                                                                               |       |       |
| <b>Dimensions</b>       | 150 mm × 4.6 mm                                                                                                                                                                                       |       |       |
| <b>Part number</b>      | AST-6016-IK46                                                                                                                                                                                         |       |       |
| <b>Mobile phase</b>     | A: PW : ACN = 95 : 5 + 0.2% H <sub>3</sub> PO <sub>4</sub><br>B: ACN : PW = 85 : 15 + 0.2% H <sub>3</sub> PO <sub>4</sub>                                                                             |       |       |
| <b>Gradient elution</b> | Time [min]                                                                                                                                                                                            | A [%] | B [%] |
|                         | 0                                                                                                                                                                                                     | 85    | 15    |
|                         | 25                                                                                                                                                                                                    | 75    | 25    |
| <b>Stop time</b>        | 25 min                                                                                                                                                                                                |       |       |
| <b>Post run</b>         | 6 min                                                                                                                                                                                                 |       |       |
| <b>Flow rate</b>        | 0.8 mL/min                                                                                                                                                                                            |       |       |
| <b>Temperature</b>      | 35 °C                                                                                                                                                                                                 |       |       |
| <b>Detection</b>        | UV @ 210 nm                                                                                                                                                                                           |       |       |
| <b>Injection volume</b> | 10 µL                                                                                                                                                                                                 |       |       |
| <b>Analytes</b>         | 1. Impurity 1<br>2. Impurity 2<br>3. Impurity 3<br>4. Impurity 4<br>5. Impurity 5<br>6. Impurity 6<br>7. Impurity 7<br>8. Impurity 8<br>9. Impurity 9<br>10. SGM: Sugammadex sodium, CAS: 343306-79-6 |       |       |



The premium product brand of Chromservis s.r.o.



Jakobiho 327/3 | 109 00 Praha 10 – Petrovice | Czech Republic | [www.chromline.eu](http://www.chromline.eu)

---

**ASTRA®** is a trademark of Chromservis s.r.o. Other trademarks and trade names may be used in this document to refer to either the entities claiming the marks and/or names or their products and are the property of their respective owners. We disclaim proprietary interest in the marks and names of others.