

PRODUCT SPECIFICATION	
<b>Product: 6-Deoxy-6-((2-carboxyethyl)sulfinyl)-heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin partly sodium salt (Mono-SO-SGM)</b> <b>Molecular formula: C<sub>72</sub>H<sub>112-n+3m</sub>N<sub>m</sub>Na<sub>n</sub>O<sub>49</sub>S<sub>8</sub></b> <b>Formula weight: 2018 + n·22 + m·17</b> <b>Quality: analytical standard</b>	Version: 01 Code: Rel_SGM_CY_3228_v01

Prepared by (QC)/date:	Revised by (QA)/date:	Approved by (QA)/date:
<i>R</i> 24 November, 2022.	<i>fy</i> 24 November, 2022	<i>[Signature]</i> 24 November 2022

Tests and methods	Requirements
Appearance# / visual	white or off-white powder
Identification 1 / LC-MS (EP 2.2.29., 2.2.43)	conforms to theoretical mass
Identification 2 / NMR (EP 2.2.33)	conforms to theoretical structure
Identification 3 / IR (EP 2.2.24)	conforms to standard
Purity as mixture of epimers <sup>#1</sup> / HPLC (EP 2.2.29)	> 90.0 area %
Distribution of epimers	to be reported
Other cyclodextrin-related impurities <sup>#1</sup> / HPLC (EP 2.2.29)	< 10.0 area %
Formate content (expressed as Sodium formate) / CE (EP 2.2.47)	< 3.0 w/w %
Sodium content <sup>2</sup> / CE (EP 2.2.47)	< 10.0 w/w%
Ammonium content / CE (EP 2.2.47)	< 10.0 w/w%
Residual solvents / TGM-MS (EP 2.2.34, 2.2.43)	< 10.0 w/w%
Purity calculated <sup>3</sup>	to be reported

# tests to extend expiry



- 1 HPLC analysis to be carried out on an Agilent Poroshell column with H<sub>3</sub>PO<sub>4</sub> / NH<sub>3</sub> buffer system at pH=2.6 and UV-Vis detection
- 2 The compound is supplied in slightly acidic form for stability reasons; the actual molar sodium content (n) is indicated on the Certificate of Analysis of each batch.
- 3 Calculated purity (w/w%) = ((100 (w/w%) - Sodium formate content (w/w%) - Residual solvents (w/w%))\*Purity (area%))/100

Comments: only for reagent and laboratory purposes, not for human use.

Storage: in deep freezer, under inert atmosphere, in tightly closed container.

*Retest date: 12 months from date of qualification.*

Version No:	Short description of change
01	First version