

PRODUCT SPECIFICATION	
Product: <b>(6-Deoxy-heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin) lactone sodium salt (Mono-LAC-SGM)</b> Molecular formula: $C_{69}H_{106-n}Na_nO_{46}S_7$ Formula weight: $1896 + n \cdot 22$ Quality: Analytical standard	Version: 01 Code: Rel_SGM_CY_3251_v01

Prepared by (QC)/date:	Revised by (QA)/date:	Approved by (QA)/date:
<i>[Signature]</i> 05 September, 2022	<i>[Signature]</i> 05. September, 2022	<i>[Signature]</i> 05. September 2022

Tests and methods	Requirements
Appearance# / visual (FIZ-05/06)	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# <sup>1</sup> / HPLC (EP 2.2.29)	> 90.0 area%
Other cyclodextrin-related impurities# <sup>1</sup> / HPLC (EP 2.2.29)	< 10.0 area%
Sodium formate content / CE (EP 2.2.47)	< 3.0 w/w%
Sodium content <sup>2</sup> / 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
- HPLC analysis to be carried out on an Agilent Poroshell column with  $H_3PO_4$  /  $NH_3$  buffer system at pH=2.6 and UV-Vis detection
  - 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.
  - Calculated purity (w/w%) =  $((100 \text{ (w/w\%)} - \text{Sodium formate content (w/w\%)} - \text{Residual solvents (w/w\%)})) \cdot \text{Purity (area\%)} / 100$



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ISO 9001



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