

PRODUCT SPECIFICATION	Version: 01 Code: Rel_SGM_CY_3245_v01
Product: 6-Deoxy-6-((1-carboxyethyl)thio)-heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin partly sodium salt (Mono-ISO-SGM) Molecular formula: C₇₂H_{112-n}Na_nO₄₈S₈ Formula weight: 2002 + n·22 Quality: analytical standard	

Prepared by (QC)/date:	Revised by (QA)/date:	Approved by (QA)/date:
7 22 November, 2022	16 22 November, 2022	22 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 ^{#1} / HPLC (EP 2.2.29)	> 90.0 area%
Distribution of epimers	to be reported
Other cyclodextrin-related impurities ^{#1} / HPLC (EP 2.2.29)	< 10.0 area%
Sodium formate content / CE (EP 2.2.47)	< 3.0 w/w%
Sodium content ² / 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 ³	to be reported

Tests to extend expiry

1 HPLC analysis to be carried out on an Agilent Poroshell column with H₃PO₄ / NH₃ 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.

<i>Version No:</i>	<i>Short description of change</i>
01	First version

