



| PRODUCT SPECIFICATION | |
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| Product: Bis(6-deoxy-heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin) disulfide partly sodium salt (SGM-SS-SGM) Molecular formula: $C_{138}H_{214-n}Na_nO_{92}S_{16}$ Formula weight: $3858 + n \cdot 22$ Quality: analytical standard | Version: 01 Code: Rel_SGM_CY_3229_v01 |

| Prepared by (QC)/date: | Revised by (QA)/date: | Approved by (QA)/date: |
|--------------------------------------|--------------------------------------|--------------------------------------|
| <i>Alk Fecser</i> 19 October 2022 | <i>László Pál</i> 19 October 2022 | <i>Alk Fecser</i> 19 October 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% |
| 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 |

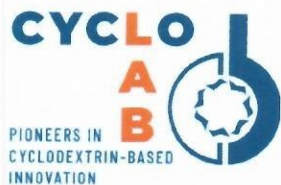
tests to extend expiry

1 HPLC analysis to be carried out on an Agilent Poroshell column with H_3PO_4 / NH_3 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

Notes: the compound is a single isomer.



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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 |