

CAPTISOL®

[Betadex (β-Cyclodextrin) Sulfobutyl Ether Sodium] USP-N.F.
Certificate of Analysis Rev 1
Batch Number: 17CX21.HE00103

Test	Specification	Result
Identification:		
Infrared Absorbance	Spectrum is consistent with the SBECD standard	Conforms
Retention Time (RT)	RT of major peak consistent with standard by Assay	Conforms
Degree of Substitution (DS)	Meets the requirements for DS by CE	6.7
Sodium	Identity tests are positive for Sodium	Conforms
Assay:		
	95.0% to 105.0% (anhydrous basis)	99.3 %
Impurities:		
Beta Cyclodextrin	Not more than 0.1%	< 0.05 %
1,4-Butane Sultone	Not more than 0.5 ppm	< 0.5 ppm
Sodium Chloride	Not more than 0.2%	< 0.02 %
4-Hydroxybutane-1-Sulfonic Acid	Not more than 0.09%	< 0.03 %
Disodium Bis(4-sulfobutyl) Ether	Not more than 0.05%	Not detected
Specific Tests:		
Bacterial Endotoxins	Not more than 6 EU/g	< 2.4 EU/g
Aerobic Microorganisms	Does not exceed 50 CFU/g	0 CFU/g
Molds and Yeasts	Does not exceed 25 CFU/g	0 CFU/g
<i>Escherichia coli</i>	Meets test requirement for absent	Conforms
<i>Salmonella sp.</i>	Meets test requirement for absent	Conforms
<i>Bile-tolerant Gram-negative bacteria</i>	Meets test requirement for absent	Conforms
<i>Pseudomonas aeruginosa</i>	Meets test requirement for absent	Conforms
<i>Staphylococcus aureus</i>	Meets test requirement for absent	Conforms
Solution Clarity	A 30% w/v solution in water is clear	Conforms
pH	4.0 to 6.8 in 30% w/v solution of carbon dioxide free water	5.9 *
Water Determination (KF)	Not more than 10.0%	5.2 %*
Appearance	White to off-white solid, essentially free foreign matter	Conforms
Average Degree of Substitution (CE)	6.2 to 6.9	6.7
	Sulfobutyl Ether Peaks I-X	% Peak Area
	I (Limit 0.0 to 0.3)	0.0
	II (Limit 0.0 to 0.9)	0.2
	III (Limit 0.5 to 5.0)	1.5
	IV (Limit 2.0 to 10.0)	5.1
	V (Limit 10.0 to 20.0)	12.6
	VI (Limit 15.0 to 25.0)	22.2
	VII (Limit 20.0 to 30.0)	27.6
	VIII (Limit 10.0 to 25.0)	20.5
	IX (Limit 2.0 to 12.0)	8.4
	X (Limit 0.0 to 4.0)	1.9

*Results obtained at time of testing, values may change depending upon exposure to atmospheric conditions.

STORAGE: Store at ambient temperature in sealed containers. Protect from moisture.

Reference: 16CX013F.HE00040-49

Item Numbers: CC-0C7-XXX, CO-0C7-XXX

Date of Manufacture: March 2023

22988569, 22315395

Item Sizes: K01, K05, K20

Solution and Final Isolation site:

Re-evaluation Date: 100 months

(1kg, 5kg, 20kg)

Hovione Ltd. Loughbeg Ringaskiddy
Ireland Cork Co

Released By:

Vincent Antle, PhD
SVP of Tech Ops & QA

Date:

08 Nov 23

*Captisol is manufactured and tested under GMP and is compliant with the USP-NF monograph for
Betadex Sulfobutyl Ether Sodium*