

Name: Sulfobutylated beta-cyclodextrin sodium salt

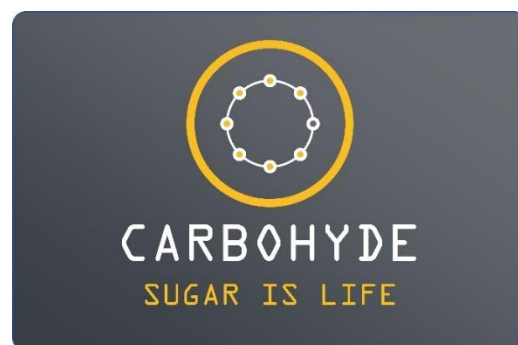
Quality: pharma grade

Average Molecular Formula

$C_{42}H_{70-n}O_{35} \cdot (C_4H_8O_3SNa)_n$

Average Formula Weight:

$1135.0 + n \cdot (158.2)$



Test	Method	Specification
Appearance	visual	White or almost white, hygroscopic powder
Identification A	IR / USP <197> EP 2.2.24	The infrared absorption spectrum is consistent with that of the standard
Identification B	HPLC / USP <621>	The retention time of the major peak of the sample solution corresponds to that of the standard solution
Identification C	CE / USP <1053>	Meets the requirements of the test for Average Degree of Substitution
Identification D / Identification B EP	Sodium ID / USP <191> EP 2.3.1	Gives the reaction of Sodium
Clarity of solution	Visual, see details in the USP Monograph EP 2.2.1 and EP 2.2.2 (Method II)	The solution is clear, and essentially free from particles of foreign matter
Reducing sugar	as in EP monograph	$\leq 0.05\%$
Assay (Calculated on the anhydrous basis)	HPLC / USP <621> EP 2.2.29	95.0% – 105.0%
Beta-cyclodextrin content	HPLC / USP <621> EP 2.2.29	$\leq 0.1\%$
1,4-butane sultone content	GC / USP <621> 2.2.28	≤ 0.5 ppm
Sodium chloride content	USP <221> EP 2.4.4	$\leq 0.2\%$
4-Hydroxybutane-1-sulfonic acid content	CE / USP <1053> HPLC / EP 2.2.29	$\leq 0.09\%$ $\leq 0.1\%$
Bis(4-sulfobutyl)-ether disodium content	CE / USP <1053> HPLC / EP 2.2.29	$\leq 0.05\%$



Test	Method	Specification
Bacterial endotoxin	USP <85> EP 2.6.14	< 0.02 EU/mg
Total aerobic microbial count	USP <61> EP 2.6.12	≤ 100 cfu/g
Total combined molds and yeasts count	USP <61> EP 2.6.12	≤ 50 cfu/g
Escherichia Coli	USP <62> EP 2.6.13	absent
Average degree of substitution	CE / USP <1053>	6.2 – 6.9
Average degree of substitution	NMR / EP 2.2.33	5.9 – 6.6
Peak distribution:		
Peak I		0 – 0.3
Peak II		0 – 0.9
Peak III		0.5 – 5.0
Peak IV		2.0 – 10.0
Peak V	CE / USP <1053>	10.0 – 20.0
Peak VI		15.0 – 25.0
Peak VII		20.0 – 30.0
Peak VIII		10.0 – 25.0
Peak IX		2.0 – 12.0
Peak X		0 – 4.0
pH	USP <791> EP 2.2.3	4.0 – 6.8
Water content	USP <921> EP 2.5.12	≤ 10%

Meets the requirements of the USP-NF and EP

Vijay Kumar