

Sulfobutyl-ether-β-Cyclodextrin sodium (SBE-β-CD), EP, USP/NF

- CAS No: 182410-00-0
- Average molecular formula: $C_{42}H_{70-n}O_{35} \cdot (C_4H_8SO_3Na)_n$
- Average formula weight: 2163 when $n=6.5$

TEST	SPECIFICATION	TEST	SPECIFICATION
Appearance	white or almost white, hygroscopic powder	Assay	98.0 - 102.0% anhydrous substance (EP) 95.0 - 105.0% on anhydrous basis (USP/NF)
Solubility	freely soluble in water, practically insoluble in anhydrous ethanol and in methylene chloride	Clarity of solution	clear and colourless
Identification		Chlorides	max. 0.12% (corresponding to 0.20 % expressed as sodium chloride)
IR	has to confirm with reference material	Water	max 10.0%
Reaction of Sodium	positive	Average degree of substitution (DS)	5.9 - 6.6 (EP) 6.2 - 6.9 (USP/NF)
HPLC	has to confirm with reference material	Residual solvents	limits according to EP, USP/NF, ICH Q3C
Reducing sugars	max. 0.05%	Microbiological analysis: TAMC, TYMC, specific microorganisms, BET (USP/NF)	tests and limits may vary depending on the use of the material
pH	5.0-7.5 (EP) / 4.0-6.8 (USP)	Storage conditions	in an airtight container
β-CD content	max. 0.1%		
1,2λ ⁶ -oxathiane-2,2-dione (EP) 1,4-Butane Sultone (USP/NF)	max. 0.5ppm		
4-hydroxybutane-1-sulfonic acid	≤0.1% (EP) ≤0.09 (USP/NF)		
4,4'-oxydi(butane-1-sulfonic acid) (EP) Bis(4-sulfobutyl) ether disodium (USP/NF)	≤0.05%		

SBE-β-CD has been designed to maximize safety and optimize interaction with drug molecules to improve the solubility, stability, bioavailability or lessen volatility, irritation, smell or taste of the drug. For β-CD, which itself has a relatively low aqueous solubility, substitution of any of the hydrogen bond-forming hydroxyl groups, even by lipophilic functions, results in a dramatic improvement in the aqueous solubility of the SBE-β-CD derivative.

Examples of API formulations containing SBE-β-CD, currently on the market: Carfilzomib, Voriconazole, Ziprasidone maleate, Posaconazole, Itraconazole and Maropitant (veterinary drug)*, Remdesivir

* Information published in Nature Reviews Drug Discovery 3, 1023-1035 (2004).

Products which are subject to patent protection are currently not offered or made available in countries where patents are in force. No orders or deliveries are possible prior to the expiry date of valid patents.