

Xi'an DELI Biochemical Industry Co., Ltd.
Certificate of Analysis

Name	* Betadex Sulfobutyl Ether Sodium
Manufacturer	Xi'an DELI Biochemical Industry Co., Ltd.
CAS NUMBER	182410-00-0
Batch weight	1500-2500 kg
Test and method	RESULTS
Description and solubility	White to off-white, amorphous powder. Freely soluble in water; sparingly soluble in methanol; practically insoluble in ethanol, in <i>n</i> -hexane, in 1-butanol, in acetonitrile, in 2-propanol, and in ethyl acetate.
Identification A	Complies with SBECD reference
Identification B	T _R of the major peak complies with SBECD reference
Identification C	Meets the requirements of the test for average degree of substitution.
Identification D	Positive test for sodium
Assay/HPLC	95.0%-105.0%
Limit of Beta Cyclodextrin(Betadex)	NMT 0.1%
Limit of 1,4-Butane Sultone	<LOD(0.06ppm)
Limit of Sodium chloride	0.05-0.10 %
Limit of 4-Hydroxybutane-1-sulfonic acid	0.01%
Limit of Bis(4-sulfobutyl) ether disodium	<LOD(0.004%)
Bacterial Endotoxins Test	<5 EU/g
Microbial Enumeration Tests	TAMC<10cfu/g TYMC<10cfu/g
Tests for Specified Microorganisms	Absence of escherichia coli/1g
Clarity of Solution(30%,w/v)	The solution is clear, and essentially free from particles of foreign matter
pH(30%,w/v)	4.0-6.8
Water Determination	NMT10.0%
Average Degree of Substitution [DS]	6.2-6.9