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## Certificate of Analysis

### 质量检验单

Product Name: Sulfobutyl Ether-beta-Cyclodextrin Sodium salt		Batch No.: 20171225
CAS No.: 182410-00-0		Quantity : 100kg
Manufacturing Date: 12/25/2017		Expired Date: 12/24/2019
Sampling Date: 12/25/2017		Report Date: 12/24/2019
Test Items	Requirements	Results
Appearance	White to off-white solid, free from foreign matter	Complies
Clarity of Solution	A 30%w/v solution in water is clear and essentially free from particles of foreign matter	Complies
Identification (IR)	Same absorption bands as USP betadex sulfobutyl ether sodium RS	Complies
Identification(Sodium)	Identify test are positive for Sodium	+
Identification (LC)	the retention time of the major peak of sample solution corresponds to the standard solution	Complies
Average Degree of Substitution	6.2-6.9	6.4
Water solution pH	pH of 30%w/v solution in water is 4.0-6.8	6.3
Heavy Metals	≤5ppm	≤5ppm
Water content	≤10.0%	5.7%
β-Cyclodextrin Content	≤0.1%	Absence
Sodium Chloride	≤0.2%	0.02%
1,4-butane sultone	≤0.5ppm	0.3ppm
4-Hydroxybutane-1-Sulfonic Acid	≤0.09%	0.01%

Disodium bis-(4-sulfobtyl) ether	≤0.05%	0.01%
Assay	95.0%-105.0%	99.8%
Bacterial endotoxins	≤20EU/g	≤10EU/g
Microbiology		
TAMC ( cfu/g)	≤100 cfu/g	<10cfu/g
TYMC ( cfu/g)	≤50 cfu/g	<10cfu/g
Escherichia Coli	Absence	Absence
Conclusion	According to USP39-NF34 standard , the product is <b>Qualified</b> .	
Packaging and storage	Preserve in well-closed containers, and store at room temperature. Protect from moisture.	
Checker : Yunxiang Han	Rechecker: Jing Zhao	Supervisor: Xuezhe Han