

**SHANDONG BINZHOU ZHIYUAN BIOTECHNOLOGY CO.,LTD.**

BOXING ECONOMIC DEVELOPMENT ZONE, BINZHOU, SHANDONG, CHINA

TEL:+86-0543-2616568 FAX:+86-0543-2605568

**COA for BETADEX SULFOBUTYL ETHER SODIUM**

CAS No.: 182410-00-0

<b>Batch No.</b>	SB20240326	<b>Packing</b>	10kg/Bag
<b>Manufacturing date</b>	2024.03.26	<b>Quantity</b>	939kg
<b>Sampling date</b>	2024.04.06	<b>Report date</b>	2024.05.06
<b>Place of sample</b>	Clean room	<b>Expiry date</b>	2027.03.25
<b>Standard</b>	USP-NF2023		
<b>ITEMS</b>		<b>CRITERIA</b>	
<b>Appearance</b>		White to off-white, amorphous powder.	Conform
<b>Solubility</b>		Freely soluble in water, sparingly soluble in methanol, practically insoluble in ethanol, in n-hexane, in 1-butanol, in acetonitrile, in 2-propanol and in ethyl acetate.	Conform
<b>Identification</b>	<b>IR</b>	Same absorption bands as USP betadex sulfobutyl ether sodium RS.	符合 Conform
	<b>HPLC</b>	The retention time of the major peak of sample solution corresponds to the standard solution.	Conform
	<b>Average degree of substitution</b>	Conform	Conform
	<b>Sodium</b>	Identify test are positive for Sodium.	Conform
<b>Assay (on the anhydrous basis)</b>		95.0%~105.0%	102.4%
<b>Betadex</b>		≤0.1%	Not detected
<b>1,4-butane sultone</b>		≤0.5ppm	0.01ppm
<b>Sodium chloride</b>		≤0.2%	0.01%
<b>4-hydroxybutane-1-sulfonic acid</b>		≤0.09%	Not detected
<b>Bis(4-sulfobutyl) ether disodium</b>		≤0.05%	0.02%
<b>Bacterial endotoxins</b>		<0.01EU/mg	<0.01EU/mg
<b>The total aerobic microbial count</b>		≤100cfu/g	<10cfu/g
<b>The total combined molds and yeasts count</b>		≤50cfu/g	<10cfu/g
<b>Escherichia coli</b>		Absence	Not detected



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Place of sample	Clean room	Expiry date	2027.03.25	
Standard	USP-NF2023			
ITEMS		CRITERIA		RESULTS
Average degree of substitution		6.2~6.9		6.4
Peaks I-X (% peak area)	I	0.0~0.3		未检出
	II	0.0~0.9		0.60
	III	0.5~5.0		2.33
	IV	2.0~10.0		6.22
	V	10.0~20.0		12.85
	VI	15.0~25.0		22.12
	VII	20.0~30.0		28.55
	VIII	10.0~25.0		19.24
	IX	2.0~12.0		6.98
	X	0.0~4.0		1.11
pH		4.0~6.8		6.1
Water determination		≤10.0%		5.8%
Clarity of solution		30%(w/v) solution is clear and essentially free from particles of foreign matter.		Conform
Packaging and storage		Preserve in well-closed containers, and store at room temperature. Protect from moisture.		
Conclusion: Compliant to the USP-NF2023				
Reporter: 孙文序	Verifier: 孙文序		Passer: 孙文序	