



CERTIFICATE OF ANALYSIS

Product Name		Sulfobutylbetadex Sodium	Batch No.	JL20250728
CAS		182410-00-0	MF Date	JUL.28,2025
Packing		20kg/Drum	Analysis Date	JUL.28,2025
Quantity		3000kg	Expiry Date	JUL.27,2027
ITEM		STANDARD		RESULT
Appearance		White or almost white,hygroscopic powder		White hygroscopic powder
Solubility		Freely soluble in water,practically insoluble in anhydrous ethanol and in methylene chloride		Conform
Identification	IR	The spectrum obtained with the substance to be examined shows the same absorption bands as the spectrum obtained with sulfobutylbetadex sodium CRS		Conform
	Sodium	Gives reactions of Sodium		Conform
Appearance of solution		Clear and colourless		Conform
pH		5.0~7.5		6.6
Reducing sugars(%)		≤0.05		0.01
Impurities A(%)		≤0.1		0.0044
Impurities C(%)		≤0.1		Absence
Impurities D(%)		≤0.05		Absence
Impurities B(ppm)		≤0.5		0.020
Sodium chloride(%)		≤0.2		<0.2
Water(%)		≤10		4
TAMC(CFU/g)		≤10 ²		10

TYMC(CFU/g)	≤50	<10
Escherichia Coli	Absence	Absence
Salmonella	Absence	Absence
Content (anhydrous substance, %)	95.0~105.0	100.8
Average Degree of Substitution(DS)	5.9~6.6	5.9
Bacterial Endotoxins(EU/mg)	<0.02	<0.02
Conclusion	Qualified	

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