



武汉福鑫化工有限公司

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CERTIFICATE OF ANALYSIS

Product: Icodextrin

Mfg. date: Jan., 17, 2022

Exp. date: Jan., 16, 2021

Lot No.: 220117FX

Quantity: Sample

Items	Specifications	Results
Appearance	White to beige powder	Conforms
Appearance of Solution	$\leq$ Y7 standard color solution	Conforms
Identification	Should conform the standard	Conforms
Assay (%)	95.0~105.0	99.8
Arsenic	Should conform the standard	Conform
Heavy Metals	Should conform the standard	Conforms
5-HMF (%)	0.25	0.12
Residue on ignition (%)	$\leq$ 0.2	0.09
Loss on Drying (120° C+2° C, %)	$\leq$ 7.0	4.2
Specific rotation (20° C, °)	+190~ +200	196.0
Escherichia Coli	Absent	Conforms
The Total Combined Molds and Yeasts Count(CFU/g)	$\leq$ 10	< 10
The Total Aerobic Microbial Count (CFU/g)	$\leq$ 50	20

Peptidoglycan(ng/g)	<10	<10
Bacterial Endotoxin (EU/g)	<1.5	<1.5
MWD (Molecular weight distribution)		
Weight-average molecular weight	13000-19000	14238
Number-average molecular weight	5000~6500	5280
<1638	≤6%	5.36%
1638- 5000	12%~ 26%	Conforms
5000~-20000	45%~ 66%	51.97%
20000- 45000	13%-23%	22.15%
1638- 45000	≥85%	92.34%
Conclusion	The product conforms to the Enterprise Standard.	

QC:

Tester:

Re-tester: