

CERTIFICATE OF ANALYSIS

Product name	Iron Sucrose	CAS No.	8047-67-4
Quantity	200kgs	Batch No.	*****
Manufacturing date	*****	Shelf life	2 years
Items	Standards		Results
Appearance	Brown to dark brown powder		Conforms
Identification A (Iron)	Conform to USP test		Conforms
Identification B (Sucrose)	The retention time of the major peak in HPLC of the assay determination corresponds to that in the chromatogram of the standard determination under assay for sucrose		Conforms
Solubility (Water)	Freely soluble		Conforms
Clearness in the solution	Clearness		Conforms
Free iron	0.4% max		0.26%
Low-molecular weight Fe(II) and Fe(III) complexes	In the polarograms obtained in the test for limit of Fe(II), no additional peaks are found		Conforms
Chloride	0.075% max		0.056%
PH	10.5-11.1		10.85
Turbidity (PH)	4.4-5.3		4.90
Specific gravity	1.135-1.165 (20°C)		1.155
Osmolarity	1150-1350 mOsmol/L		1280 mOsmol/L
Alkalinity	0.5-0.8ml/ml		0.65 ml/ml
Mw	34000-60000 Da		44500
Mn	24000 Da min		32000
Mw/ Mn	1.7 max		1.39
Loss on drying	5.0% max		2.1
Heavy metals (Plumb; Copper; Zinc)	25ppm max		Conforms
Arsenic	4ppm max		Conforms
Assay- sucrose	80% min(on as is basis)		87.6%
Assay-Iron	5.3-6.0%(on as is basis)		5.66%
Residual solvents	Not applied		Not applied
Conclusion	Complying with USP		

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