

CERTIFICATE OF ANALYSIS

Product name	Ferric Carboxymaltose	CAS No.	9007-72-1
Quantity	300kgs	Batch No.	*****
Manufacturing date	*****	Shelf life	2 years
Items	Standards		Results
Appearance	Red brown powder		Conforms
Solubility	Soluble in water and almost insoluble in ethanol		Conforms
Identificaiton			
Iron	Positive		Positive
Dextrin	Conforms		Conforms
Molecular Weight	Conforms		Mw:168KD Mn:123KD Mw/Mn:1.4
pH （5%w/vFe）	5.0—7.0		5.8
Osmolality （5%w/vFe）	220—380mOsmol/kg		328mOsmol/kg
Limit of Iron (I)	≤1.2%		0.10%
Chloride Content	≤6.0%		2.20%
Residual solvents	≤1.2%		0.01%
Loss on drying	≤10.0%		3.70%
Arsenic	NMT 2ppm		0.01ppm
Copper	NMT 320ppm		3.2ppm
Lead	NMT 10ppm		0.02ppm
Bacteria Endotoxins	NMT 0.1Eu/mg Fe		Conforms
Total Aerobic Bacteria	NMT 100CFU/g		Conforms
Total Mold And Yeast	NMT 10CFU/g		Conforms
Escherichial coli	Absent/g		Conforms
Pseudomonsas aeruginosa	Absent/g		Conforms
Staphylococcus aureus	Absent/g		Conforms
Assay of dextrin (on anhydrous basis)	25.0%~50.0%		42.80%
Assay of Iron (on anhydrous basis)	24.0%~32.0%		27.50%
Conclusion	Qualified		