

CERTIFICATE OF ANALYSIS

Version 2.0

Revision Date: 04/14/2016

PRODUCT IDENTIFICATION

Product identifiers

Product Name : Inulin for Injection in 0.9% NaCl, USP
 Catalog Number : FIT-0408
 Current Lot : **16041101**

USP Test	Procedure	Specification	Result	Pass/Fail
Completeness of Solution	Inulin Monograph	Solution must be clear	Clear	Pass
Specific Rotation	USP <781S>	between -32.0 and -40.0	-35.5	Pass
Microbial Enumeration Tests	USP <61>	The total aerobic microbial count is less than 1000 per g.	≤ 100 cfu/g	Pass
Tests for Specified Microorganisms	USP <62>	Absence of Salmonella species and Escherichia coli and for absence of Staphylococcus aureus and Pseudomonas aeruginosa.	Absent	Pass
Loss on Drying	USP <731>	≤ 10%	3.1%	Pass
pH	USP <791>	4.5 – 7.0	5.3	Pass
Chloride	USP <221>	≤0.014%	≤0.014%	Pass
Iron	Inulin Monograph	Conforms to Test	Conforms to Test	Pass
Reducing Sugars	Inulin Monograph	Conforms to Test	Conforms to Test	Pass
Calcium	Inulin Monograph	≤ 0.10%	≤ 0.10%	Pass
Sulfate	USP <221>	≤ 0.05%	≤ 0.05%	Pass
Heavy Metals	USP <231>	≤ 5 ppm	≤ 5ppm	Pass
Residue on Ignition	USP <281>	≤(% of Ca found X 3.4)1.05	0.07%	Pass
Free Fructose	Inulin Monograph	≤ 2%	1.1%	Pass
Content of combined glucose	Inulin Monograph	≥2% ≤5%	3.5%	Pass
Assay for Inulin	Inulin Monograph	≥94% ≤102%	100.4%	Pass
Clarity of Solution		The solution is clear	Clear	Pass
Assay for sodium chloride		8.55 – 9.45 g/L		Pass
ELISA sensitivity		Comparable sensitivity to past lots		Pass
Autoclaved		Follow mSOP specifications		Pass