

Dextran Products Standard Operating Procedures

S.O.P.# QC3407-09

Title: Liquid Iron Dextran 20% Specifications




Effective Date: APR 28 2021

Supersedes: SOP #QC3407-08

Page 1 of 1

FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance	Dark brown slightly viscous liquid
Identification	Passes (Identification for Iron Dextran Injection, USP)
pH:	4.5 to 7.0
Iron Content	19.0% to 21.0% (w/v)
Chloride Content	0.8% to 1.1% (w/v)
Dextran Content	14.0% to 23.0% (w/v)
Total Free Iron Content	NMT 0.30% (w/v)
Free Ferrous Ion Content	NMT 0.20% (w/v)
Free Ferric Ion Content	NMT 0.30% (w/v)
Non-Volatile Residue	45.0% to 60.0% (w/v)
Phenol Content	NMT 0.5% (w/v)
Relative Viscosity at 25°C	NMT 30
Endotoxins	NMT 0.50 EU/mg
Absorption from Injection Site	Passes (In-House Method)
Acute Toxicity	Passes (Acute Toxicity for Iron Dextran Injection, USP)
Total Aerobic Microbial Count	NMT 50 CFU/mL

Written By: 	Title: Analytical Chemist	Date: April 27, 2021
Revised By: 	Title: QC Manager	Date: April 27, 2021
Approved By: 	Title: QA Manager	Date: April 27, 2021

Dextran Products, Scarborough, Ontario, M1L 2H5, Canada