



TECHNICAL DATA SHEET
Resonant Circuits Limited
www.resonantcircuits.com
Version x.xx

Product name	RCL-01
Reference	RCL2001
Volume (ml)	0.5
Product description	Magnetic dextran iron oxide nanoparticles in water for injection (WFI) with saline.
Manufacturing conditions	cGMP cleanroom ISO class 8
Sterilisation method	Gamma irradiation 25-40 kGy
Storage	+2 to +8 °C (do not freeze)

Parameter	Result
Mean particle diameter (Z-average, nm)	149
Polydispersity index (PI)	0.26
Particle concentration (mg/ml)	188
Iron concentration (mg _{Fe} /ml)	72
Osmolality (mOsmol/kg)	299
AC-Susceptibility (25 kHz, 10 ⁻³ m ³ /kg _{Fe})	10.2
ILP (nHm ² /kg _{Fe})***	5.1
Endotoxin concentration (EU/ml)*	0.4
Microorganism contamination (cfu/ml)**	<1

* Turbidimetric-kinetic method, Ph.Eur. 8.0 (2014) 2.6.14, USP (2012) <85> 38 NF 33

** Membrane filtration method, DIN EN ISO 11737-1

*** Measured at 5 kA/m at 1 MHz