

<b>CERTIFICATE OF ANALYSIS</b>	<b>IRON CROMAZUROL</b>
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<b>REF</b>	1135105	2 x 50 mL	X	CT10272	3 x 60 ml	x	1938005	1 x 3 mL	X
	1135185	1 x 5 L	X				1938080	1 x 0.5 L	X
	1135150	50 ml/80 un		1938006	3 ml/60 un	x	1938081	1 x 1 L	X

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15568		2019-06	<b>IVD</b>
	<b>Standard</b>	<b>X</b>	<b>LOT</b>				2-8°C

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Maroon. Liquid. Clear. Free of particles.	ACCEPTED	X
	CAL	Brown. Liquid. Clear. Free of particles.	ACCEPTED	X
pH	R1	4.7 ± 0.2	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

<b>1. Analytical parameters</b>	<i>Blank.</i> Absorbance of Working reagent against water. <i>Sensitivity.</i> A <sub>635</sub> / 100 µg/dL Iron <sub>standard</sub> <i>Linearity.</i> Higher level established by the analytical performance. <i>Accuracy.</i> Ratio between assigned and obtained Iron values.
<b>2. Stability Testing</b>	<i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Items kept at 37/42°C for a stated period of time.

<b>INSTRUMENT</b>	SHIMADZU/BS300	635nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>635</sub> ≤ 0.575	ACCEPTED	ACCEPTED
Sensitivity	0.090-0.120	ACCEPTED	ACCEPTED
Linearity	Up to 1000 µg/dL	ACCEPTED	ACCEPTED
Accuracy	Within the expected values	ACCEPTED	ACCEPTED

(ACCEPTED / N/A)

This lot was assayed by the test method described in the manufacturer's package insert. These results are applicable to this lot and subsequent sublots, for which a capital letter has been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

<b>This lot meets our specifications and is released for sale</b>	APPROVED	<b>Signed</b> <b>Date of Manufacture</b> Mayte Lázaro 2017-05-30 Quality Control Dept.
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