



WORK AND TEST PROTOCOL

DESCALE, DEROUGING & PASSIVATION

Date: 12/30/2012

Client: XYZ PHARMA

Project/Quote no: _____

System type: WFI loop and CSG

Material: 316 ss

Signature List	Name	Signature	Initials
1. Technician	John Jones		JJ
2. Technician			

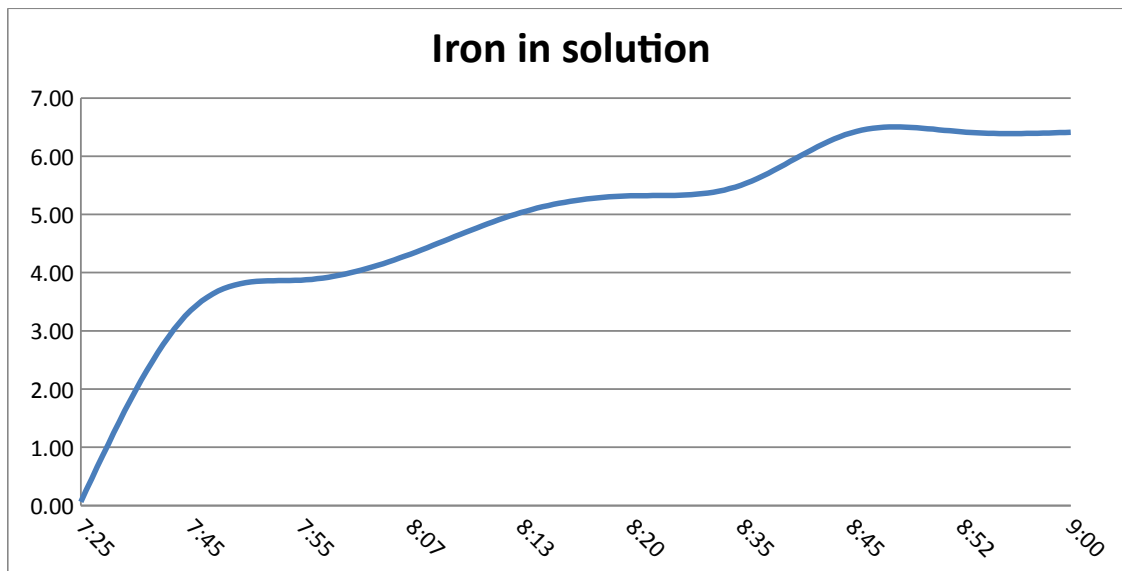
Leak test		Start	Stop	Acceptance criteria	Accepted	Initials
Test	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	7:00	7:15	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Visual check	No leaks		No leakage	YES	JJ

Derouging		Start	Stop	Acceptance criteria	Accepted	Initials
Preparation	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Water Reservoir (L)	5,152		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Temperature (°C)	85		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Purge the system with Nitrogen gas (N ₂)	N/A	N/A	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	O ₂ concentration	N/A		≤ 1.0 %	YES	JJ
	Lot No. Diruneutra LIQ	174293 (2), 174292 (1), 161927 (2)		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Quantity (L)	100		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Concentration	1.94		1.75 – 2.26 % v/v	YES	JJ
	Temperature (°C)	85		≥ 70°C	YES	JJ
	Lot No. Diruneutra P	174362 (1), 174336 (4)		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Quantity (kg)	30		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Concentration	0.58		0.5 – 0.7 % w/v	YES	JJ

Derouging	Date	29-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	7:30	9:00	60 – 240 min.	YES	JJ
	Temperature (°C)	85		70 – 85°C	YES	JJ
	pH	5.6		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Circulation	Yes		Yes	YES	JJ

Total Iron in solution

Time	Fe (ppm)	Activity
7:25	0.06	Baseline
7:45	3.35	active
7:55	3.87	active
8:07	4.32	active
8:13	5.03	active
8:20	5.32	active
8:35	5.50	active
8:45	6.40	active
8:52	6.42	active
9:00	6.41	active



Rinse 1

		Start	Stop	Acceptance criteria	Accepted	Initials
Pre Rinsing (NS)	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Lot No. Duruclean NS	174256 (2), 174253, 174273, 161905		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Quantity (L)	22.5		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Concentration	0.44		0.35 – 0.65 % v/v	YES	JJ
	Time	9:00	9:50	≥ 45 min	YES	JJ
	Temperature (°C)	85		30 – 85°C	YES	JJ
	pH	5.6		N.A.	YES	JJ
Draining	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	9:50	10:15	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
Rinse	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	10:15	10:45	≥ 5 min	YES	JJ
	Temperature (°C)	30		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ

Evaluation / Test

			Acceptance criteria	Accepted	Initials
Visual Test	Date	30-Dec	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	11:00	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	The surface is clean	YES	Clean	YES	JJ

Passivation

		Start	Stop	Acceptance criteria	Accepted	Initials
Preparation	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Water Reservoir (L)	5152		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Temperature (°C)	30		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Lot No.	HB120848636		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Hydrogen Peroxide	832		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Quantity (L)	832		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Concentration	5.7%		5% – 8 % v/v	YES	JJ
Passivation	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	11:30	12:45	≥ 60 μv	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Temperature (°C)	30		≤ 45	YES	JJ
	pH	6.0		pH ≥ 5	YES	JJ
	Circulation	Yes		Yes	YES	JJ

Rinse 2

		Start	Stop	Acceptance criteria	Accepted	Initials
Draining	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	12:45	13:00	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
Rinse	Date	30-Dec		N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ
	Time	13:00	13:30	N.A.	<input type="checkbox"/> yes <input type="checkbox"/> no	JJ

Remarks

UltraClean Electropolish Inc. confirms that the treatment was successfully performed:

Confirmation by	Name	Date	Signature
UltraClean Electropolish	John Jones	12/31/2012	