

List of Equipment & Utility Systems Qualification

Number of Equipment	Documentation by Supplier	Tests Execution by Supplier	Documentation by Consultant	Tests Executed by Consultant	Writing of Protocols Qty	SOPs Qty	Total Documents Qty	Execution of Potocols Qty	Turn Over Package	Equipment
LOT 1 – Autoclaves, Washer				Sub-Total	5	6	11	5	3	
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	2	2	4	2	1	Autoclave
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	2	2	4	2	1	Autoclave Solid Waste
1	SAT, IQ, OQ, PQ	SAT, IQ, OQ, PQ	IOQ Umbrella, PQ	IOQ Umbrella	1	2	3	1	1	Part Washer
LOT 2 – Fridge, Freezer, Incubators				Sub-Total	63	10	73	63	19	
1			IQ, OQ, PQ	IQ, OQ, PQ	9	2	11	9	1	Cold room
2			IQ, OQ, PQ	IQ, OQ, PQ	6	2	8	6	2	Freezer -20C
6			IQ, OQ, PQ	IQ, OQ, PQ	18	2	20	18	6	Fridge 4C
5			IQ, OQ, PQ	IQ, OQ, PQ	15	2	17	15	5	Incubator
5			IQ, OQ, PQ	IQ, OQ, PQ	15	2	17	15	5	Freezer -80C
LOT 3 – Bioreactors, Chromatography, TFF & Filling, Mixing tanks				Sub-Total	43	28	71	85	27	
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 2000L SU
1	IQ, OQ	IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 20L Wave
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 500L SU
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 50L SU
2	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	2	2	4	2	2	Chromatography AEX/MMC
2			IQ, OQ	IQ, OQ	2	2	4	2	2	Chromatography column
2	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	2	2	4	2	2	TFF (UF/DF)
6	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	12	2	14	24	6	Mixer 50 L Single Use
1	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	2	2	4	4	1	Mixer 100 L Single Use
5	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	10	2	12	30	5	Mixer 200 L Single Use
2	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	4	2	6	8	2	Mixer 500 L Single Use
1	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	2	2	4	4	1	Mixer 1000 L Single Use
1	FAT, SAT, IQ, OQ	FAT, SAT	IOQ Umbrella, PQ	IQ, OQ, IOQ Umbrella, PQ	2	2	4	4	1	Mixer 2500 L Single Use
1	FAT, SA, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Isolator / Filling system
LOT 4 –HVAC, Biosafety Cabinet & Weight Booth**				Sub-Total	69	8	77	69	23	
12			IQ, OQ, PQ	IQ, OQ, PQ	36	4	40	36	12	HVAC Systems (Nb)
8			IQ, OQ, PQ	IQ, OQ, PQ	24	2	26	24	8	Biosafety cabinet
3			IQ, OQ, PQ	IQ, OQ, PQ	9	2	11	9	3	Weight booth
LOT 5 – Packaging				Sub-Total	11	14	25	11	7	
1			IQ	IQ	1	2	3	1	1	Accumulation table
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Labeler**
1			IQ, OQ	IQ, OQ	2	2	4	2	1	Denester
1			IQ, OQ	IQ, OQ	2	2	4	2	1	Semi-automatic case erector and sealer
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Cartoner**
1			IQ, OQ	IQ, OQ	2	2	4	2	1	Inspection station
1	IQ, OQ	IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Print and apply**
			PQ	PQ	1		1	1		Packaging Line
LOT 6 – Small Equipment				Sub-Total	51	28	79	59	53	
4			IOQ	IOQ	4	2	6	4	4	Cell counter
2			IOQ	IOQ	2	2	4	2	2	Cell thaw (water-free thawing system)
6			IOQ, PQ	IOQ, PQ	12	2	14	12	6	Filter integrity tester
13			IOQ	IOQ	13	2	15	13	13	Balance

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2			IOQ	IOQ	2	2	4	2	2	Microcentrifuge
2			IOQ	IOQ	2	2	4	2	2	Microscope
8			IOQ	IOQ	8	2	10	8	8	pH meter/Conductivity meter
1	IQ, OQ			IOQ		2	2	1	1	Portable Air sampler
5	IQ, OQ			IOQ		2	2	5	5	Portable biosealer
1	IQ, OQ			IOQ		2	2	1	1	Portable CO2 reader for incubator
1	IQ, OQ			IOQ		2	2	1	1	Portable VHP decontamination system
5			IOQ	IOQ	5	2	7	5	5	Tube welder
1			IOQ	IOQ	1	2	3	1	1	Thermowelder for wrap
2			IOQ	IOQ	2	2	4	2	2	Transfer Filtration system
LOT 7 - CSV**				Sub-total	2	8	10	8	2	
1	SAT, IQ, OQ		IOQ umbrella	SAT, IQ, OQ, IOQ	1	4	5	4	1	MIT System
1	SAT, IQ, OQ		IOQ umbrella	SAT, IQ, OQ, IOQ	1	4	5	4	1	EMS System
LOT 8 - Water Systems				Sub-total	7	10	19	15	3	
1	FAT, SAT, IQ, OQ		IOQ Umbrella, PQ	FAT, SAT, IQ, OQ, IOQ umbrella, PQ	2	4	7	6	1	Purified Water System
1	FAT, SAT, IQ, OQ		IOQ Umbrella, PQ	FAT, SAT, IQ, OQ, IOQ umbrella, PQ	2	4	7	6	1	Water for injectable (WFI) + Pure Steam generator
1			IQ, OQ, PQ	IQ, OQ, PQ	3	2	5	3	1	MilliQ System
LOT 9 – Non GMP Systems				Sub-total	2	4	2	0	2	
1			SAT	SAT	1	2	1		1	Biological effluent System
1			SAT	SAT	1	2	1		1	Wastewater treatment syste,
				TOTAL	253	116	367	315	139	
*Execution of protocols includes writing of closure reports										
** Those equipment will require a TM										