

# 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	6	6	12	6	3	
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	2	2	4	2	1	Autoclave - Sterilization
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	2	2	4	2	1	Autoclave Solid Waste
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	2	2	4	2	1	Part Washer
LOT 2 – Fridge, Freezer, Incubators				Sub-Total	24	12	36	28	10	
1			IQ, OQ, PQ	IQ, OQ, PQ	3	2	5	3	1	Cold room
2			IQ, OQ, PQ	IQ, OQ, PQ	6	2	8	6	2	Freezer -20C
1			IQ, OQ, PQ	IQ, OQ, PQ	3	2	5	3	1	Media Refrigerator 2-8C
2	IQ,OQ	IQ,OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	4	2	6	4	2	Cryofreezers Liquid Nitrogen
2	FAT, SAT, IQ, OQ	FAT,SAT	PQ	IQ, OQ, PQ	2	2	4	6	2	Shaker Incubator
2			IQ, OQ, PQ	IQ, OQ, PQ	6	2	8	6	2	Freezer -80C
LOT 3 – Bioreactors, Chromatography, TFF & Mixers				Sub-Total	37	14	51	37	37	
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Benchtop Bioreactor 25L SU
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 500L SU, inc. TCU
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	bioreactor 50L SU, inc. TCU
2	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	2	2	4	2	2	Chromatography AEX/MMC
11	SAT, IQ, OQ	SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	11	2	13	11	11	Single use mixers (different size), inc. 5 TCU
20	IQ, OQ	IQ, OQ	IOQ Umbrella	IOQ Umbrella	20	2	22	20	20	Tanks, different size, inc. 5 TCU
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	TFF (UF/DF)
LOT 4 –HVAC, Biosafety Cabinet & Weight Booth**				Sub-Total	35	8	43	35	14	
7			IQ, OQ, PQ	IQ, OQ, PQ	21	4	25	21	7	HVAC Systems (Nb)
5			IQ, OQ	IQ, OQ	10	2	12	10	5	Biosafety cabinet
2	IQ,OQ	IQ,OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	4	2	6	4	2	Weight booth
LOT 5 – Small Equipment				Sub-Total	37	38	75	39	36	
1			IOQ	IOQ	1	2	3	1	1	Cell counter
1			IOQ	IOQ	1	2	3	1	1	De-Freezer (Thawing unit)
2	IQ,OQ	IQ,OQ	IOQ Umbrella, PQ	IOQ Umbrella, PQ	4	2	6	4	2	Filter integrity tester
11			IOQ	IOQ	11	2	13	11	11	Balance (Floor and benchtop)
1			IOQ	IOQ	1	2	3	1	1	Refrigerated Benchtop Centrifuge
1			IOQ	IOQ	1	2	3	1	1	Metabolite analyser
4			IOQ	IOQ	4	2	6	4	4	pH meter/Conductivity meter
1			IOQ	IOQ	1	2	3	1	1	SD Viral inactivation skid
1			IOQ	IOQ	1	2	3	1	1	Nanofiltration skid
2			IOQ	IOQ	2	2	4	2	2	Magnetic stirrer
3			IOQ	IOQ	3	2	5	3	3	Portable Air sampler
1			IOQ	IOQ	1	2	3	1	1	TOC Analyser
1			IOQ	IOQ	1	2	3	1	1	Portable bioealer
2	IQ, OQ	IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Portable welders
1			IOQ	IOQ	1	2	3	1	1	Osmometer
1	IQ, OQ	IQ, OQ	IOQ Umbrella	IOQ Umbrella	1	2	3	1	1	Portable VHP decontamination system
1	IQ, OQ			IQ, OQ	0	2	2	2	1	Spectrophotometer
1			IOQ	IOQ	1	2	3	1	1	Laminar flow hood

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1			IOQ	IOQ	1	2	3	1	1	Tangencial flow filtration
LOT 6 - CSV**				Sub-total	1	4	5	4	1	
1	SAT,IO, OQ		IOQ umbrella	SAT, IQ, OQ, IOQ	1	4	5	4	1	EMS System
LOT 7 - Clean Utilities				Sub-total	21	20	41	21	8	
1	FAT,SAT	FAT,SAT	IQ, OQ, PQ	IQ,OQ,PQ	3	4	7	3	1	Purified Water System
1	FAT, SAT, IQ, OQ	FAT, SAT, IQ, OQ	IOQ Umbrella, PQ	IOQ umbrella, PQ	2	4	6	2	1	Water for injectable (WFI) + Pure Steam generator
1	SAT	SAT	IQ, OQ, PQ	IQ, OQ, PQ	1	2	3	1	1	WFI distribution system
1	SAT	SAT	IQ, OQ, PQ	IQ, OQ, PQ	3	2	5	3	1	Pure Steam Distribution System
3			IQ, OQ, PQ	IQ, OQ, PQ	9	6	15	9	3	CO2, N2, O2 distribution systems
1			IQ, OQ, PQ	IQ, OQ, PQ	3	2	5	3	1	Clean compressed air and distribution
LOT 8 – Non GMP Systems				Sub-total	1	2	3	1	1	
1			SAT	SAT	1	2	3	1	1	Biological effluent System
				TOTAL	162	104	266	171	110	
*Execution of protocols includes writing of closure reports										
** Those equipment will require a TM										