

21 CFR Part 11 QC Instrument Suite



QC Step	Instrument	Application	Regulation	A	L	C	O	A
Raw Material	ANATEL PAT700	On-line Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC), Temperature and Conductivity	USP<643> USP<645> EP2.2.44 EP2.2.38	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	QbD1200	Grab-sample point of use testing for Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC),	USP<643> EP2.2.44	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	LS 13 320 XR	Active Pharmaceutical Ingredient, Excipients	ISO 13320	Multi-level, individual User Name and Password for all users		Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
Production	Vi-CELL BLU	Mammalian cell viability and concentration	USP <1046>	Multi-level, individual User Name and Password for all users	Legible secure PDF export for measurement results	Secure data records stored and tracked at time of measurement	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	Vi-CELL MetaFLEX	Mammalian cell bioreactor media health		Multi-level, individual User Name and Password for all users	Legible reports can be printed or viewed on the instrument	Secure data records stored and tracked at time of measurement	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	MET ONE 3400	Routine environmental monitoring (air particulates) in sterile manufacturing cleanrooms	EU GMP Annex 1 CGMP ISO 14644-1 & -2	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Measurement Results including metadata	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	MET ONE Facility Monitoring System	Sterile manufacturing cleanroom continuous air particulate monitoring	EU GMP Annex 1 CGMP ISO 14644-2	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure data records stored in database at time of measurement	Original electronic record created directly from the instrument	Your SOPs pre-programmed into the User Interface and automated. No manual data entry or Pass/Fail calculations
Final Product Testing	HIAC 9703+	Final product sub-visible particulate counting in parenteral drug products	USP<787> USP<788>	Multi-level, individual User Name and Password for all users		Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	DelsaMax	Stability testing protein formulations (protein aggregations)	USP<787>					SOP parameters pre-programmed into the instrument and automated
	Multisizer 4e	Final product visible particulate inspection in opaque parenteral drug products	USP<790>					SOP parameters pre-programmed into the instrument and automated

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QC Step	Instrument	Application	Instrument set-up	Sample ID	Report	Review & Approve	Root Cause Investigation
Raw Material	ANATEL PAT700	On-line Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC), Temperature and Conductivity	SOP parameters pre-programmed into the instrument and automated	Report tied to S/N of PAT700, name of water loop and time and date stamped	Secure PDF electronic file created by instrument		Water sample captured by PAT700 automatically for root cause investigation if alarm level passed
	QbD1200	Grab-sample point of use testing for Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC),	SOP parameters pre-programmed into the instrument and automated	Sample ID and lot number can be tied to electronic record	Secure PDF electronic file created by instrument		Instrument self-check on daily start-up – failed components recorded to facilitate root cause investigation
	LS 13 320 XR	Active Pharmaceutical Ingredient, Excipients	SOP parameters pre-programmed into the instrument and automated	Sample ID and lot number can be tied to electronic record	Secure PDF electronic file created by instrument		
Production	Vi-CELL BLU	Mammalian cell viability and concentration	SOP parameters pre-programmed into the instrument and automated	Sample ID and lot number can be tied to electronic record	Secure PDF electronic file created by instrument	Digital signatures can be applied to data result	Cell viability and count measurement data stored for re-analysis to support root-cause analysis
	Vi-CELL MetaFLEX	Mammalian cell bioreactor media health	SOP parameters pre-programmed into the instrument and automated	Sample ID tied to electronic record	Reports can be automatically printed by the instrument at the end of the measurement or on demand	Digital signatures can be applied to data result	Automatic QC and Calibration stored and correlated to data result. Can be reviewed for trouble-shooting
	MET ONE 3400	Routine environmental monitoring (air particulates) in sterile manufacturing cleanrooms	SOP parameters pre-programmed into the instrument and automated	Sample location name and optional batch ID tied to electronic record	Secure PDF electronic file created by instrument		User can enter root-cause text into electronic record should an alarm occur to support root-cause investigations if alarm triggered
	MET ONE Facility Monitoring System	Sterile manufacturing cleanroom continuous air particulate monitoring	SOP parameters pre-programmed into the instrument and automated	Batch number and sample location ID tied to each electronic record	Secure PDF electronic file created by system.	Digital signatures can be applied to batch report.	Digitally signed alarm acknowledgement with comment.
Final Product Testing	HIAC 9703+	Final product sub-visible particulate counting in parenteral drug products	SOP parameters pre-programmed into the instrument and automated	Sample ID and lot number can be tied to electronic record	Secure PDF electronic file created by instrument	Reviewer electronic signature attached to electronic record	
	DelsaMax	Stability testing protein formulations (protein aggregations)	SOP parameters pre-programmed into the instrument and automated				

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