

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82943-11	Equipment Name:	ACQUITY SDS Automated Test System	
Installation Site: Flex, Singapore				
Purpose: To verify that supporting documentation is available prior to the completion of qualification.				
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #		Status in SAP	Initial & Date
TSP	ACQUITY BSM PUMP AUTOMATED FINAL TEST TEST PROCEDURE, 735002010 REVISION P, VERSION 13		RELEASE GENERAL	HZ 22 OCT 2020
CAL	CALIBRATION/MAINTENANCE FOR TE82943, ACQUITY SDS AUTOMATED TESTER, 735001828, REVISION E, VERSION 04		RELEASE GENERAL	HZ 22 OCT 2020
Comments:				
Overall Test Conclusion			Document No.: _____	
☒ Pass ☐ Fail			Iteration No.: _____	
			Attachment: _____ Page: ____ of ____	

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82943-11	Equipment Name:	ACQUITY SDS Automated Test System		
Installation Site: Flex, Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).					
Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.					
Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description		Acceptance Criteria	As Found	Pass/Fail	Initial & Date
ACQUITY SDS Final Test Station System Software		Version: 2.4	Version: 2.4	PASS	HZ 22 OCT 2020
Comments:					
Overall Test Conclusion			Document No.: _____		
☒ Pass ☐ Fail			Iteration No.: _____		
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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82943-11	Equipment Name:	ACQUITY SDS Automated Test System	
Installation Site: Flex, Singapore				
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy. Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.				
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 186015061 Serial Number: J20BBS001G		All required CTQ Specification measurements result in a Pass	PASS	HZ 22 OCT 2020
Comments:				
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☒ Pass ☐ Fail				