

INSTALLATION QUALIFICATION REPORT

For the ACQUITY SDS Final Test System (TE82943-18)

PREPARED BY

Name	Role	Signature	Date
Ernest Chua	Process Validation Engineer		29 JAN 21

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

Name	Role	Signature	Date
Luo Huazhen	Senior Test Engineer		01 Feb 2021

The "Reviewed By" signatures denotes agreement with the description of the qualification activities.

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

VERSION:	06	ORIGINATOR:	Ernest Chua	Change ID:	N/A
SUMMARY OF CHANGE: Update of QSM program to 2.0 in order to add part number 186018001, Premier QSM Pump Assembly					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of 730004135, Installation Qualification Protocol, for the TE82943-18, ACQUITY SDS Final Test System.

1.1 SYSTEM BACKGROUND

The TE82943-18, ACQUITY SDS Final Test System, facilitates the final functional test of ARC QSM, BSM, ISM, M Class, QSM, and UPC2 solvent managers. Each family of products is tested on a unique test program according to the corresponding Test and Specification Procedure, as shown in the Table below:

TE82943-ACQUITY SDS FINAL TEST SYSTEM - PROGRAMS	
PRODUCT/PROGRAM	TEST AND SPECIFICATION PROCEDURE
ARC QSM	735003612
BSM	735002010
ISM	735002977
M-Class	735003807
QSM	735002155
UPC2	735002690

The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP Test Specification and Procedure 735002155, Rev M, Version 11 for the TE82943-18, ACQUITY SDS Final Test System.

In the final test, the UUT is connected to the system and the electrical, mechanical and fluidic performance of the unit are tested. Upon completion of all testing, a Final Test Record is to be kept and maintained locally or on SigmaSure Database.

The ACQUITY SDS Final Test System TE82943-18 is located at Flex, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82943-18, ACQUITY SDS Final Test System, based on the requirements of the executed protocol, 730004135 Ver. 03, Installation Qualification Protocol, as detailed in TE82943-16JUL2020-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82943-18, ACQUITY SDS Final Test System was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE82943-18, ACQUITY SDS Final Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82943-18, ACQUITY SDS Final Test System can be considered fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
ARC	Acquity Reduced Cost
BSM	Binary Solvent Manager
cGMP	Current Good Manufacturing Practice
CTQ	Critical to Quality
IQR	Installation Qualification Report
ISM	Isocratic Solvent Manager
N/A	Not Applicable
P/N	Part Number
QSM	Quaternary Solvent Manager
SAP	Enterprise Resource Planning Software
SDS	Solvent Delivery System
TSP	Test Specification and Procedure
UPC2	Ultra-Performance Convergence Chromatography
UUT	Unit Under Test
VAF	Validation Assessment Form

5.0 TRAINING

The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. The training records are provided as Attachments 7.1.

The operator of the TE82943-18, ACQUITY SDS Final Test System was trained according to the Test Specification and Procedures 735002155, Rev M, Version 11. The training records are provided as Attachment 7.2.

6.0 QUALIFICATION RESULTS

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Test Specification and Procedure 735002155, Rev M, Version 11 was confirmed to be in SAP with a status of Release General. A screen capture is provided below:

Document List After Selection 12 Hits

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Choose Save Thumbnails (Images)

RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	TSP	735002155	00	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		23.04.2010	31.01.2011	9151370	Edward Jackson
B	TSP	735002155	01	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		01.02.2011	26.09.2013	9158885	Edward Jackson
C	TSP	735002155	02	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		27.09.2013	25.03.2015	9183181	Edward Jackson
D	TSP	735002155	03	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		26.03.2015	26.08.2015	9196131	Edward Jackson
E	TSP	735002155	04	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		27.08.2015	05.11.2015	9199306	Edward Jackson
F	TSP	735002155	05	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		06.11.2015	03.01.2018	9201928	Daniel Guertin
G	TSP	735002155	06	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		04.01.2018	04.07.2018	9218986	Edward Jackson
H	TSP	735002155	07	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		05.07.2018	15.04.2019	9221407	Edward Jackson
J	TSP	735002155	08	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		16.04.2019	08.09.2019	9228666	Edward Jackson
K	TSP	735002155	09	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		09.09.2019	19.02.2020	9229308	Edward Jackson
L	TSP	735002155	10	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		20.02.2020	09.11.2020	9232558	Edward Jackson
M	TSP	735002155	11	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		10.11.2020	31.12.9999	9236073	Edward Jackson

6.1.2 The 735001828 Rev E, Version 04, the Calibration/Maintenance for TE82943 was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as follows:

RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	CAL	735001828	00	000	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL		09.09.2008	07.07.2010	9137807	Edward Jackson
B	CAL	735001828	01	000	AcQuity SDS Automated Tester Calibration	RELEASE GENERAL		08.07.2010	16.07.2012	9153643	Edward Jackson
C	CAL	735001828	02	000	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL		17.07.2012	25.08.2013	9172278	Edward Jackson
D	CAL	735001828	03	000	Calibration/Maintenance for TE82943	RELEASE GENERAL		26.08.2013	31.01.2016	9182185	Edward Jackson
E	CAL	735001828	04	000	Calibration/Maintenance for TE82943	RELEASE GENERAL		01.02.2016	31.12.9999	9204087	Edward Jackson

6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.4.

6.2.1 The Test Equipment Software version listed in 735002155, Rev M, Version 11 is Test Software 2.0. The test record of passing result is provided as Attachment 7.6.

6.2.2 The instrument firmware listed for P/N 186018001 is Version 1.72.415. A screen capture from the SAP is as follows:

Item	Ict	Component	Component description	Quantity	Un	Asm	SIs	Valid
0010	L	279004403	ASSY, QSM, PREMIER	1	EA	☒	☐	06.
0020	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	06.
0030	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	06.
0040	L	290001182	BOX, ACQUITY SOLVENT MODULE	1	EA	☐	☐	06.
0060	L	361000828	ACQUITY QSM firmware 1.72.415	1	EA	☐	☐	06.
0080	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	06.
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	06.
0100	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	06.
0110	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	06.
0120	L	700012811	ASSY, TUBING, BIO PUMP OUTLET	1	EA	☒	☐	02.

6.3 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.3.1 One (1) UUT (P/N: 186018001) was tested using the TE82943-18, ACQUITY SDS Final Test System with all tests passing, meeting the acceptance criteria of all required CTQ Specification measurements/conditions. The screenshot of passing result is provided as Attachment 7.6.

6.4 This table provides a summary of each test script as performed according to 730004135, Ver. 03 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3	None
IQ-04	Pass	Attachments 7.4 and 7.6	None
IQ-06	Pass	Attachments 7.5 and 7.6	None

7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record 730004135, Ver. 03
- 7.2 Completed Operator Training Record 735002155, Rev M, Version 11
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Completed Test Script IQ-06: Functional Verification
- 7.6 Objective Evidence IQ-04 and IQ-06: Test record of passing UUT (P/N: 186018001)

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the 730004135, Installation Qualification Procedure, Version 03, for TE82943-18, Acquity SDS Final Test System.

9.0 REFERENCES

The following documents are referenced within this Report:

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735002155, Rev M, Version 11	Test Specification and Procedure, Acquity QSM Final Instrument Test
735001828 Rev E, Version 04	Calibration/Maintenance for TE82943
TE82943-16JUL2020-VAF	Validation Assessment Form (VAF) for the ACQUITY SDS Final Test Program – QSM Program

Title: Individual Training Form

Document No: 730002657

Version No: 01

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Training Type:	Read and Understood		
Name:	Ernest Chua	Employee ID:	618144
Date of Training:	26 AUG 2020		
Comments:	N/A		

Document Number	Title	Rev #
730004135	Installation Qualification Protocol	03
	N/A <i>ding</i> 26 AUG 2020	

ding

Process Validation Engineer

26 AUG 2020

Employee's Signature

Title

Date

N/A Self-trained

ding

26 AUG 2020

Trainer's Signature

Title

Date

Document No.: TE82943-18-IQRIteration No.: 06Attachment: 7.1 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

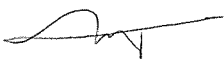
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Appendix A: TRAINING RECORD

Document #	735002155	Document Title	Acquity QSM Final Instrument Test	Version	11
				Revision	M

☒ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
Joel Mamalateo Deduyo		JMD	19 JAN 21
N/A			

Print multiple copies of this Training Record Template as needed

Document No.: TE82943-18-IQR

Iteration No.: 06

Attachment: 7.2 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82943-18	Equipment Name:	ACQUITY SDS Final 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 QSM FINAL INSTRUMENT TEST TEST PROCEDURE, 735002155 REVISION M, VERSION 11	RELEASE GENERAL	EC 29 JAN 21	
CAL	CALIBRATION/MAINTENANCE FOR TE82943, ACQUITY SDS AUTOMATED TESTER, 735001828, REVISION E, VERSION 04	RELEASE GENERAL	EC 29 JAN 21	
Comments: N/A <i>Xing</i> 29 JAN 2021				
Overall Test Conclusion		Document No.: <u>TE82943-18-IQR</u>		
☒ Pass ☐ Fail		Iteration No.: <u>06</u>		
		Attachment: <u>7.3</u> Page: <u>01</u> of <u>01</u>		

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82943-18	Equipment Name:	ACQUITY SDS Final 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: 2.0	Version: 2.0	PASS	EC 29 JAN 21	
Comments: N/A <i>Xing</i> 29 JAN 2021					
Overall Test Conclusion		Document No.: TE82943-18-IQR			
☒ Pass ☐ Fail		Iteration No.: 06			
		Attachment: 7.4 Page: 01 of 01			

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82943-18	Equipment Name:	ACQUITY SDS Final 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: 186018001 Serial Number: A21PQS001A		All required CTQ Specification measurements result in a Pass	PASS	EC 29 JAN 21
Comments: N/A <i>Xing</i> 29 JAN 2021				
Overall Test Conclusion			Document No.: <u>TE82943-18-IQR</u> Iteration No.: <u>06</u> Attachment: <u>7.5</u> Page: <u>01</u> of <u>01</u>	
☒ Pass ☐ Fail				

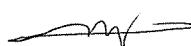
Waters Corporation - Test Record

Part Number: <u>186018001</u>	Product: <u>Acquity Premier QSM</u>
Operator: <u>246154</u>	Start Time: <u>01/27/2021, 09:09:</u>
Serial Number: <u>A21PQS001A</u>	End Time: <u>01/27/2021, 13:43:</u>
Test System: <u>TE82943-18</u>	Order: <u>N/A</u>
Test Software: <u>2.0</u>	Location: <u>Flextronics, SG</u>

Firmware: 1.72.415 (Aug 7 2018 10:20:14)

Name	LSL	Measurement	USL	Unit	Outcome
Test Electrical Safety					PASS
Test Loader Download					PASS
Test Reboot Firmware					PASS
Test Firmware Version					PASS
Test Instrument Type					PASS
Test Serial Number					PASS
Test Alarms at Bootup					PASS
Test Gradient Start Input SHORT					PASS
Test Gradient Start Input OPEN					PASS
Test Stop Flow Input SHORT					PASS
Test Stop Flow Input OPEN					PASS
Test Leak Detect Connected					PASS
Test Leak Detect Disconnected					PASS
Test Leak Detect Leak					PASS
Test Alarms Recheck					PASS
Test Seal Wash Pump Prime/Flow	2	3.4	5	ml/min	PASS
Test Input D Prime with MeOH	10	30.2	85	PSI	PASS
Test Input C Prime with MeOH	10	29.7	85	PSI	PASS
Test Input B Prime with MeOH	10	28.9	85	PSI	PASS
Test Input A Prime with MeOH	10	28.8	85	PSI	PASS
Test Degasser Pressure	0	0.72	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	43	149.9	nL/min	PASS
Test Dynamic Leak - Accumulator Percent of Stroke	1	24	30	%	PASS
Test Dynamic Leak - Accumulator Compressed Volume	1	14	50	uL	PASS
Test Dynamic Leak - Accum. Maximum Pressure	14000	14028	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	28	149.9	nL/min	PASS
Test Dynamic Leak - Primary Percent of Stroke	1	24	50	%	PASS
Test Dynamic Leak - Primary Compressed Volume	1	14	50	uL	PASS
Test Dynamic Leak - Primary Maximum Pressure	12000	12017	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	2.017	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	4	15	PSI	PASS
Test Flow Rate Accuracy 0.5ml/min	0.495	0.502	0.505	ml/min	PASS
Test Static Leak Decay Vent Valve to Filter/Mixer	1	16	250	PSI/min	PASS
Test High Pressure	9000	10600	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	90.04	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	89.76	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	10.05	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.25	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity Premier QSM Final Test Overall Result - PASS

Signed: 246154 	Date: 27 JAN 2021
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END OF DATA

Ser. No.: A21PQS001A

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Document No.: TE82943-18-IQR
Iteration No.: 06
Attachment: 7.6 Page: 01 of 01