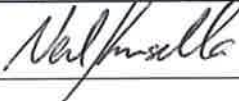


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VALIDATION REPORT for the LC Test Equipment

PREPARED BY

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APPROVED BY

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

The "Reviewed By" signature[s] denotes agreement with the description of the validation activities.

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

REVISION HISTORY

Version	Author	Date	Summary of change
00	Neil Kinsella	29-May-2013	First document for approval

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1.0 Introduction

This Validation Report details the validation activities undertaken for the LC Test Equipment based on the requirements of the Validation Plan 0251-VP, Revision 01.

This document has been written in accordance with the global procedure Process V: Validation Report Procedure [730000903].

2.0 Scope

This Report details the activities undertaken to validate the LC Test Equipment as per the validation plan (0251-VP). This Report defines the processes and documents that validated the LC Test Equipment. The LC test equipment has been in operation in Waters, Wexford for two years. The manufacturer of these products is now being transferred to Venture in Singapore. This validation exercise was used to verify that the LC test equipment operates in Venture as it did in Wexford. The validation was done in two phases. Phase one was a bench marking exercise done in Wexford and was used to benchmark the state of the equipment as it was operating in Wexford. Phase two was done in Singapore and this validation was used to verify that the performance of the equipment had not changed as a result of the relocation.

The validation approach has been to provide documented evidence of the functionality of the LC Test Equipment using the Waters risk-based approach to compliant cGMP systems.

3.0 Deviation from Validation Plan

There are no deviations from the approach detailed in the Validation Plan (0251-VP).

All of the activities defined in the Validation Plan have been completed and all defined documents have been generated and formally approved.

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4.0 Summary of Activities

As detailed in the Validation Plan, the final validation documentation package comprises the following:

Document Type	Document Reference	Version Number	Pre Approval Date	Final Approval Date
Validation Plan	0251-VP	01	N/A	19 Apr 2013
IQ, OQ and PQ Protocols	0257-IQ	00	03 Apr 2013	01 May 2013
	0257-OQ	00	03 Apr 2013	26 Apr 2013
	0258-IQ	00	08 Apr 2013	26 Apr 2013
	0258-OQ	00	08 Apr 2013	01 May 2013
	0259-IQ	00	17 Apr 2013	01 May 2013
	0259-OQ	00	17 Apr 2013	01 May 2013
	0260-IQ	00	08 Apr 2013	29 Apr 2013
	0260-OQ	00	17 Apr 2013	29 Apr 2013
	0261-IQ	00	08 Apr 2013	29 Apr 2013
	0261-OQ	00	08 Apr 2013	01 May 2013
	0262-IQ	00	17 Apr 2013	29 Apr 2013
	0262-OQ	00	17 Apr 2013	01 May 2013
	0269-IQ	00	25 Apr 2013	30 Apr 2013
	0270-IQ	00	26 Apr 2013	30 May 2013
	0270-OQ	01	25 Apr 2013	31 May 2013
	0271-IQ	00	25 Apr 2013	31 May 2013
	0271-OQ	01	26 Apr 2013	31 May 2013
	0272-IQ	00	25 Apr 2013	31 May 2013
	0272-OQ	00	25 Apr 2013	30 May 2013
	0273-IQ	00	26 Apr 2013	30 May 2013
	0273-OQ	00	26 Apr 2013	31 May 2013
	0274-IQ	00	26 Apr 2013	31 May 2013
	0274-OQ	00	26 Apr 2013	31 May 2013
	0275-IQ	00	26 Apr 2013	31 May 2013
	0275-OQ	00	26 Apr 2013	31 May 2013
	0276-IQ	00	26 Apr 2013	30 May 2013
Validation Report (this document)	0251-VR	00	N/A	31 May 2013

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5.0 Test Results

All protocols were successfully executed and no deviations were raised see details in table below.

Equipment Name	Site	Document No.	Result (P/F)	Deviation No.
Lamp Alignment Station	Wexford	0257-IQ	Pass	n/a
		0257-OQ	Pass	n/a
FLR Optics Bench Alignment Station	Wexford	0258-IQ	Pass	n/a
		0258-OQ	Pass	n/a
2475 Optics Bench Alignment Station	Wexford	0259-IQ	Pass	n/a
		0259-OQ	Pass	n/a
2475/FLR Firmware	Wexford	0260-IQ	Pass	n/a
		0260-OQ	Pass	n/a
Final Test Station No.1	Wexford	0261-IQ	Pass	n/a
		0261-OQ	Pass	n/a
Final Test Station No.2	Wexford	0262-IQ	Pass	n/a
		0262-OQ	Pass	n/a
Hi-Pot Tester	Wexford	0269-IQ	Pass	n/a
Lamp Alignment Station	Venture	0270-IQ	Pass	n/a
		0270-OQ	Pass	n/a
FLR Optics Bench Alignment Station	Venture	0271-IQ	Pass	n/a
		0271-OQ	Pass	n/a
2475 Optics Bench Alignment Station	Venture	0272-IQ	Pass	n/a
		0272-OQ	Pass	n/a
2475/FLR Firmware	Venture	0273-IQ	Pass	n/a
		0273-OQ	Pass	n/a
Final Test Station No.1	Venture	0274-IQ	Pass	n/a
		0274-OQ	Pass	n/a
Final Test Station No.2	Venture	0275-IQ	Pass	n/a
		0275-OQ	Pass	n/a
Hi-Pot Tester	Venture	0276-IQ	Pass	n/a

5.1 Lamp Alignment Station

The IQ results for the Lamp Alignment Station validation (0257-IQ and 0270-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Lamp Alignment Station in Wexford and the Lamp Alignment Station in Venture.

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The OQ for the Lamp Alignment Station (0257-OQ and 0270-OQ) in test OQ-09 required that 6 lamps (3 x 2475 and 3 x FLR) be aligned on the Alignment Station in Wexford and screen shots be taken of the aligned lamps. These lamps were then sent to Venture and put on the alignment station over there and screen shots were taken of the aligned lamps in Venture. The Wexford screen shots and the Venture screen shots have been compared and there is no significant difference between them.

The OQ for the Lamp Alignment Station in test OQ-06 documents the operation of the Lamp Alignment Station HMI and it can be concluded that the Lamp Alignment operates in Venture as it did in Wexford.

5.2 FLR Optics Bench Alignment Station

The IQ results for the FLR Optics Bench Alignment Station validation (0258-IQ and 0271-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Optics Bench Alignment Station in Wexford and the Optics Bench Alignment Station in Venture.

The OQ for the FLR Optics Bench Alignment Station validation (0258-OQ and 0271-OQ) in test OQ-09 required that 3 FLR Optics benches be aligned using the alignment station in Wexford and then sent to Venture and their alignment was checked on the alignment station in Venture. This produces 6 sets of results (3 from each site). These results are shown in the table below.

	Wexford	FLR					Venture	FLR			
Serial No.			Test 1	Test 2	Test 3	Serial No.			Test.1	Test 2	Test 3
FLR-GLD	Wavelength	415-417nm	415.1	415.2	415	FLR-GLD	Wavelength	415-417nm	415.2	415.9	415.2
	Sample Energy	>7	12.7	12.1	12.3		Sample Energy	>7	12.9	12.4	12.8
	Ram-ray Ratio	>0.15	0.52	0.52	0.53		Ram-ray Ratio	>0.15	0.53	0.54	0.53
	Val-ram Ratio	<30	23.04	23.16	22.75		Val-ram Ratio	<30	22.61	23.04	22.92
	Reference Energy	>700	825.3	838.2	819.9		Reference Energy	>700	841.6	819.7	822.5
3723572-04	Wavelength	415-417nm	416.2	416	416	3723572-04	Wavelength	415-417nm	416.3	416.3	416.3
	Sample Energy	>7	23.6	22.7	25		Sample Energy	>7	22.8	25.2	22.6
	Ram-ray Ratio	>0.15	0.44	0.45	0.45		Ram-ray Ratio	>0.15	0.32	0.33	0.33
	Val-ram Ratio	<30	18.31	18.55	18.19		Val-ram Ratio	<30	22.67	21.82	22.75
	Reference Energy	>700	750.6	741	750		Reference Energy	>700	936.3	930.2	920
3723572-07	Wavelength	415-417nm	415.4	415.4	415.5	3723572-07	Wavelength	415-417nm	415.3	415.3	415.4
	Sample Energy	>7	27.1	24.2	25.6		Sample Energy	>7	25.1	24.4	24.7
	Ram-ray Ratio	>0.15	0.57	0.57	0.56		Ram-ray Ratio	>0.15	0.57	0.57	0.57
	Val-ram Ratio	<30	16.15	16.05	16.21		Val-ram Ratio	<30	16.59	16.69	16.8
	Reference Energy	>700	707.2	709.2	707.1		Reference Energy	>700	730.7	705.5	735.3

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The results from the Wexford validation show no significant difference from the results from the Venture Validation.

A T-Test was done on the data generated from each of the validations and the results from this test are shown below. The t-test assesses whether the means of two groups are statistically different from each other. If the resulting P value from a T-test is above 0.05 this means that the test data is statically the same at a 95% confidence level.

Wavelength P-value = 0.493

Sample Energy P-value = 0.927

Ram-ray Ratio P-value = 0.413

Val-ram Ration P-value = 0.308

Reference Energy P-value = 0.080

As can be seen all P values are greater that 0.05 so the test results show that the data from the two sites are the same.

5.3 2475 Optics Bench Alignment Station

The IQ results for the 2475 Optics Bench Alignment Station validation (0259-IQ and 0272-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Optic Bench Lamp Alignment Station in Wexford and the Optics Bench Alignment Station in Venture.

The OQ for the 2475 Optics Bench Alignment Station validation (0259-OQ and 0272-OQ) in test OQ-09 required that 3 2475 Optics benches be aligned using the alignment station in Wexford and then sent to Venture and their alignment was checked on the alignment station in Venture. This produces 6 sets of results (3 from each site). These results are shown in the table below.

Wexford						Venture					
Serial No.		2475	Test 1	Test 2	Test 3	Serial No.		2475	Test 1	Test 2	Test 3
3731394-07	Wavelength	396-398nm	397.4	397.4	397.4	3731394-07	Wavelength	396-398nm	397.5	396.8	396.9
	Sample Energy	>20	61.5	64.2	57.7		Sample Energy	>20	59.3	58.9	56.7
	Ram-ray Ratio	>1	1.27	1.28	1.24		Ram-ray Ratio	>1	1.25	1.21	1.27
	Val-ram Ratio	<50	40.17	42.66	42.68		Val-ram Ratio	<50	40.22	42.54	42.45
	Reference Energy	>1600	1773.9	1787.6	1761.5		Reference Energy	>1600	1744.1	1731.4	1729.1
3731394-08	Wavelength	396-398nm	396.8	396.8	396.8	3731394-08	Wavelength	396-398nm	397.1	397.1	397
	Sample Energy	>20	50.3	51	55.4		Sample Energy	>20	55.8	53	51.4
	Ram-ray Ratio	>1	1.24	1.25	1.25		Ram-ray Ratio	>1	1.3	1.28	1.28
	Val-ram Ratio	<50	49.6	49.57	48.61		Val-ram Ratio	<50	48.19	48.68	47.21
	Reference Energy	>1600	1628.8	1632.3	1628.61		Reference Energy	>1600	1645.7	1623.9	1632
2475GOLD	Wavelength	396-398nm	397.9	397.9	397.8	2475GOLD	Wavelength	396-398nm	397.1	397	397.3
	Sample Energy	>20	38.4	36.7	36.4		Sample Energy	>20	43.5	39.4	40.2
	Ram-ray Ratio	>1	1.06	1.07	1.08		Ram-ray Ratio	>1	1.1	1.07	1.03
	Val-ram Ratio	<50	46.83	46.45	45.87		Val-ram Ratio	<50	46.06	48.82	49.5
	Reference Energy	>1600	1858.3	1834.3	1819.9		Reference Energy	>1600	1853	1858	1944.7

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The results from the Wexford validation show no significant difference from the results from the Venture Validation.

A T-Test was done on the data generated from each of the validations and the results from this test are shown below. The t-test assesses whether the means of two groups are statistically different from each other. If the resulting P value from a T-test is above 0.05 this means that the test data is statically the same at a 95% confidence level.

Wavelength	P-value = 0.144
Sample Energy	P-value = 0.871
Ram-ray Ratio	P-value = 0.907
Val-ram Ration	P-value = 0.932
Reference Energy	P-value = 0.934

As can be seen all P values are greater that 0.05 so the test results show that the data from the two sites are the same.

5.4 Firmware Download Station

The IQ results for the Firmware Download Station validation (0260-IQ and 0273-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Firmware Download Station in Wexford and the Firmware Download Station in Venture.

The OQ results for the Firmware Download Station (0260-OQ and 0273-OQ) have also been compared and it can be concluded that the Firmware Download Station operates in Venture as it did in Wexford.

5.5 Final Test Station No.1

The IQ results for the Final Test Station No.1 validation (0261-IQ and 0274-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Final Test Station No.1 in Wexford and the Final Test Station No.1 in Venture.

The OQ for the Final Test Station No.1 validation (0261-OQ and 0274-OQ) in test OQ-09 required that 2 x FLR and 2 x 2475 detectors be tested 5 times using the final test station in Wexford and then sent to Venture and tested again 5 times using the final test station in Venture. This produces 40 sets of results (20 from each site). These results are shown in the table below.

	Wexford	Final Test No.1					
Instrument No.			Test No.1	Test No.2	Test No.3	Test No.4	Test No.5
2475 No.1	Rayleigh	350+/-2.5nm	351.8	351.6	351.7	351.8	350.5
2475 No.1	Raman	397+/-2.5nm	397.5	396.6	396.7	396.7	394.8
2475 No.1	Noise	1000<N<4000	2437.07	2381.48	2266.89	2354.67	2154.09
2475 No.2	Rayleigh	350+/-2.5nm	350.9	350.9	350.8	350.8	351.4
2475 No.2	Raman	397+/-2.5nm	396	395.9	396.6	396.6	396.5
2475 No.2	Noise	1000<N<4000	2016.07	2140.76	2121.14	2072.11	2316.04
FLR No.1	Rayleigh	365+/-2.5nm	364.7	364.8	364.9	364.8	365.5

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FLR No.1	Raman	416+/-2.5nm	416.8	416.2	417	416.9	416.8
FLR No.1	Noise	1000<N<4000	3272.16	3502.28	3145.11	3119.52	3059.81
FLR No.2	Rayleigh	365+/-2.5nm	365.1	365.2	365.2	365.3	365.2
FLR No.2	Raman	416+/-2.5nm	416.6	416.6	416.6	416.7	416.7
FLR No.2	Noise	1000<N<4000	2157.2	2598.2	2247.79	2874.47	2374.6

	Venture	Final Test No.1					
Instrument No.			Test No.1	Test No.2	Test No.3	Test No.4	Test No.5
2475 No.1	Rayleigh	350+/-2.5nm	351.4	351.5	351.5	351.4	351.4
2475 No.1	Raman	397+/-2.5nm	396.4	396.5	396.5	395.7	396.4
2475 No.1	Noise	1000<N<4000	233.01	2464.2	2555.81	2499.69	2642.01
2475 No.2	Rayleigh	350+/-2.5nm	350.7	350.7	350.8	350.9	350.9
2475 No.2	Raman	397+/-2.5nm	396.5	395.8	396.7	396.7	395.9
2475 No.2	Noise	1000<N<4000	2014.98	2049.18	2009.08	2100.52	1980.7
FLR No.1	Rayleigh	365+/-2.5nm	365.3	365.2	365.2	365.2	364.5
FLR No.1	Raman	416+/-2.5nm	416.7	416.7	416.6	416.7	416.7
FLR No.1	Noise	1000<N<4000	2750.51	2801.88	2893.31	3182.63	2555.08
FLR No.2	Rayleigh	365+/-2.5nm	365.3	364.8	364.8	364.8	364.8
FLR No.2	Raman	416+/-2.5nm	416.7	416.1	416.9	416.8	416.8
FLR No.2	Noise	1000<N<4000	3180.87	3377.29	3207.22	2841.43	3296.17

The results from the Wexford validation show no significant difference from the results from the Venture Validation.

A T-Test was done on the data generated from each of the validations and the results from this test are shown below. The t-test assesses whether the means of two groups are statistically different from each other. If the resulting P value from a T-test is above 0.05 this means that the test data is statically the same at a 95% confidence level.

Rayleigh P-value = 0.968

Raman P-value = 0.988

Signal/Noise Ratio P-value = 0.995

As can be seen all P values are greater than 0.05 so the test results show that the data from the two sites are the same.

5.6 Final Test Station No.2

The IQ results for the Final Test Station No.2 validation (0262-IQ and 0275-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Final Test Station No.2 in Wexford and the Final Test Station No.2 in Venture. The OQ for the Final Test Station No.2 validation (0262-OQ and 0275-OQ) in test OQ-09 required that 2 x FLR and 2 x 2475 detectors be tested 5 times using the final test station in Wexford and

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then sent to Venture and tested again 5 times using the final test station in Venture. This produces 40 sets of results (20 from each site). These results are shown in the table below.

	Wexford	Final Test No.1					
Instrument No.			Test No.1	Test No.2	Test No.3	Test No.4	Test No.5
2475 No.1	Rayleigh	350+/-2.5nm	350.9	350.9	351.6	352.3	352.5
2475 No.1	Raman	397+/-2.5nm	395.2	395.2	396.6	395.8	397.5
2475 No.1	Noise	1000<N<4000	2070.89	2529.66	2565.47	2395.3	2312.38
2475 No.2	Rayleigh	350+/-2.5nm	350.7	350.7	350.6	350.7	350.8
2475 No.2	Raman	397+/-2.5nm	395.8	395.8	395.7	396.5	395.9
2475 No.2	Noise	1000<N<4000	1920.08	2149.43	2076.31	2169.51	2235.27
FLR No.1	Rayleigh	365+/-2.5nm	364.5	365.2	365.2	365.2	365.2
FLR No.1	Raman	416+/-2.5nm	416.7	416.7	416.7	416.7	416.7
FLR No.1	Noise	1000<N<4000	2648.34	2645.17	2494.89	3050.05	2087.93
FLR No.2	Rayleigh	365+/-2.5nm	364.8	365.4	364.8	364.8	364.8
FLR No.2	Raman	416+/-2.5nm	416.2	416.7	416.9	416.9	416.1
FLR No.2	Noise	1000<N<4000	3122.28	2380.28	1965.71	1707.08	1514.07

	Venture	Final Test No.1					
Instrument No.			Test No.1	Test No.2	Test No.3	Test No.4	Test No.5
2475 No.1	Rayleigh	350+/-2.5nm	351.8	350.4	351.8	351.8	352.8
2475 No.1	Raman	397+/-2.5nm	397.5	396.1	397.5	397.6	398.3
2475 No.1	Noise	1000<N<4000	2154.57	1886.75	1616.3	1469.21	1158.18
2475 No.2	Rayleigh	350+/-2.5nm	351.3	351.4	351.5	351.5	351.5
2475 No.2	Raman	397+/-2.5nm	396.3	396.4	396.4	396.5	396.5
2475 No.2	Noise	1000<N<4000	2231.54	2104.86	2447.55	2486.89	2520.03
FLR No.1	Rayleigh	365+/-2.5nm	365.2	365.2	365.2	365.3	365.2
FLR No.1	Raman	416+/-2.5nm	416.6	416.6	416.7	418.5	416.7
FLR No.1	Noise	1000<N<4000	2906	2882.81	2524.98	2948.72	2399.46
FLR No.2	Rayleigh	365+/-2.5nm	364.8	364.1	364.9	364.9	367.5
FLR No.2	Raman	416+/-2.5nm	416.9	416.3	417	417	418.5
FLR No.2	Noise	1000<N<4000	3368.42	3295.21	3321.95	3488.39	3691.82

The results from the Wexford validation show no significant difference from the results from the Venture Validation.

A T-Test was done on the data generated from each of the validations and the results from this test are shown below. The t-test assesses whether the means of two groups are statistically different from each other. If the resulting P value from a T-test is above 0.05 this means that the test data is statically the same at a 95% confidence level.

Rayleigh P-value = 0.885

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Raman P-value = 0.839

Signal/Noise Ratio P-value = 0.188

As can be seen all P values are greater than 0.05 so the test results show that the data from the two sites are the same.

5.7 Hi-pot Tester

The IQ results for the Hi-pot Tester validation (0269-IQ and 0276-IQ) have been compared and it can be concluded that there is no significant differences between the installation of the Hi-pot Tester in Wexford and the Hi-pot Tester in Venture.

6.0 Training

All Wexford and Venture staff that were involved in the validation were fully trained on the equipment and the validation protocols. The training records that were used to document this are attached to the protocol that they apply too.

7.0 Maintaining Compliance and Fitness for Intended Use

All changes to hardware and software, instrumentation and documentation should follow Waters Milford Change Control and configuration management procedures.

8.0 Conclusion - Statement of Fitness for Intended Use

After a comparison of the results from the Wexford and Venture validations, it can be concluded that there is no significant difference between the installation and operation of the LC test equipment between the two sites.

Waters now has the necessary documentation in place to enable Waters management and regulatory inspectors to audit the project and ensure that the LC Test Equipment complies with Waters' requirements, the latest relevant quality system regulations and cGMP practices.

Following the approval of this Validation Report, LC Test Equipment can be considered fully validated. Any subsequent changes to the LC Test Equipment will be subject to the Change Control Procedure.

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9.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
PVAF	Process Validation Assessment Form
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
TR	Test Report
VR	Validation Report