

SCIEX Triple Quad™ 4500 System Operational Qualification (OQ) Protocol

Instrument Serial Number: BI21751305

Protocol Start Date: 08-Julio-2024

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11.3. ATTACHMENT CROSS-REFERENCE55

1. Operational Qualification (“OQ”) Preapproval

1.1. Review and approve this OQ Protocol according to the procedures and quality system requirements of the organization that owns the instrument. The customer and other required personnel must sign (in ink) below. SCIEX recommends that other departments in the customer’s organization that are affected by the outcome of the OQ process review and approve this OQ Protocol.

1.2. Approve the OQ Protocol before the FSE executes it by completing the approvals below. Add more signatures as

required. Fill in any blank spaces below with “N/A,” indicating “Not Applicable.”

1.3. The completion of the approvals below indicates that the SCIEX Triple Quad™ 4500 System OQ Protocol:

- Has been reviewed and approved by the customer and other required personnel in the organization that owns the instrument.
- Is ready to be executed.

01393576///

Pre-approval Signatures				
Name	Signature	Initials	Title/Role	Date
ADAN ALPIZAR		AAM	SCIENTIFIC DIRECTOR	08-julio-2024



2. Document Revision History

Revision History		
Revision	Description	Validity Date
G	Section 5.3 – added Storage, retention and maintenance of the completed qualification protocol that is provided upon completion of the qualification service Test 9.4.1 – updated Test Procedure from Service Diagnostic software tool to service software tool, updated Acceptance Criteria with Tuning Tools criteria, updated Actual Results table with Tuning Tools option Test 10.5.3 – replaced ASD software with service software tool Test 10.5.4 – replaced Analyst Service Diagnostic Utility with service software tool Test 10.8.1 – deleted Analyst Replaced MCA with MCA or Σ throughout document	December 2021

Revision History

Revision	Description	Validity Date
F	<p>Updated disclaimer, page 2</p> <p>Removed From/To from Revision History Table</p> <p>Removed completed Verification Data Sheets and from Section 3.2</p> <p>Replaced OQ Protocol with OQ Service in Section 5.5</p> <p>replaced inserted into the envelope at with attached to in Section 6.5</p> <p>Added Attachments must include: to Section 6.5</p> <p>Added Section 6.5.1 and 6.5.2</p> <p>Updated Section 8 Recommendations for Re-Qualification</p> <p>Updated Section 9 Pre-Execution Verification to include Section Summary Table</p> <p>Updated Section 9 to include Field Service Training Verification, Customer Information, Field Service Work Order Verification, Tools Verification and Chemical Kit Verification sections</p> <p>Updated Section 10 to include System Hardware Identification, System Software Identification, System Maintenance Verification, Power On, Electronic modules, and Voltage Verification, Operational Verification – Pre-Test Pressure Verification, Operational Verification – Chemical Tests – Triple Quadrupole. Operational Verification – Ion Source Tests, Operational Verification – Post-Test Pressure Verification, OQ Completion Verification sections</p> <p>Added Δ Mass (Da) Specification for Q1 (+/-) and Q3 (+/-) Tests No. 10.7.1-10.7.4</p> <p>Updated from Place the printouts of spectra, complete with the method file information, in the envelope in the back of this protocol. to Attach printouts of spectra, with peak intensities, peak width, and mass shift results, complete with the method file information, to the back of this protocol throughout document</p> <p>Added Test No. 10.5.2 , 10.5.3, 10.5.5 and 10.8.2</p> <p>Updated Test No. 10.5.4 for Entrance Potential (Q0), Interquad Lens 1 (IQ1), Stubby 1 (ST1) to .0 Set Voltages (Max/Min) specificity</p> <p>Removed Note: Run test as described in the <i>SCIEX Triple Quad™ 4500 System Installation Guide</i>. Use Acceptance Criteria in this document to evaluate results.</p> <p>Added No Exceptions to Test No. 10.10.2 Actual Results</p> <p>Removed Part Number 4466005 from last page of document</p>	March 2020
E	Rebranding AB SCIEX to SCIEX. Remove references to <i>SCIEX MS System SW/FW/Device Compatibility Matrix</i> .	May 2015





Revision History

Revision	Description	Validity Date
D	SCIEX Triple Quad™ 4500 System Operation Qualification Protocol	December 2014
C	SCIEX Triple Quad™ 4500 System Operation Qualification Protocol	August 2013
B	SCIEX Triple Quad™ 4500 System Operation Qualification Protocol	February 2013
A	SCIEX Triple Quad™ 4500 System Operation Qualification Protocol	March 2012

3. Purpose

3.1. This OQ Protocol is used to verify:

- The operation of a newly installed SCIEX Triple Quad™ 4500 System (SYSTEM).
- The operation of a system that has previously been verified using an SCIEX OQ Protocol, but has subsequently undergone service, repair, upgrade, or maintenance that is critical to the performance of the SYSTEM.
- The operation of a system that has site requirements for a scheduled operational qualification.

See Section 8 for more information about when to perform a SYSTEM re-qualification.

3.2. The execution of this OQ Protocol results in an OQ documentation package that includes identified attachments.

3.3. The OQ Protocol is used to verify that the SYSTEM, at the time of testing, is operating in accordance with SCIEX specifications.

3.4. Any exceptions from SCIEX specifications encountered during the execution of this OQ Protocol will be recorded. Exception conditions will be investigated and the appropriate course of action determined. The SCIEX FSE will record all results in this OQ Protocol.

4. Scope

4.1. This OQ Protocol specifically applies only to the SYSTEM as configured and installed according to SCIEX specifications. This OQ Protocol does not apply to any software, other products, processes, or optional components, unless specifically stated in this document.

4.2. This OQ Protocol does not address any customer-specific analytical protocol, performance qualification, or method validation.

4.3. The content of this document has been developed according to SCIEX understanding of the system. SCIEX makes no

representation whatsoever that this OQ Protocol or OQ service satisfies or will satisfy any requirements of any governmental body or other organization. The customer acknowledges and agrees that the customer is responsible for meeting their governing regulatory and certification requirements.

5. Responsibilities

5.1. SCIEX developed this OQ Protocol for the SYSTEM and is responsible for revision control of the OQ Protocol.

5.2. The SCIEX FSE who performs this OQ Protocol is responsible for:

- Recording all findings and test results completely.
- Verifying that results are within the specifications described or that exceptions are recorded in the Exception Report and attached at the back of this OQ Protocol.
- Initialing and dating each task to indicate that the task was completed.
- Signing, initialing, and dating the FSE Final Approval line when the Qualification procedure is complete.

5.3. The customer is responsible for:

- Meeting the site requirements as outlined in the SYSTEM site planning guide.
- Reviewing the entries made by the FSE and accepting these entries by signing under "Reviewed by." This signifies customer agreement with the entries made.
- Resolving exceptions arising from events outside of SCIEX control such as misplaced user documentation or inability to comply with instrument site requirements.
- Completing the OQ Protocol and Report Approval Signatures according to the procedures of the customer's organization.
- Storage, retention and maintenance of the completed qualification protocol that is provided upon completion of the qualification service

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5.4. In the event that a new instrument in the process of installation does not meet the operational specifications or other requirements in this OQ Protocol, SCIEX will be responsible, to the extent covered by an SCIEX warranty, for effecting repair of the instrument to verify that operational specifications are met. If SCIEX execution of this OQ Protocol is interrupted by an instrument or power failure due to mains power loss or disruption, SCIEX may, at its option, terminate the execution of this OQ Protocol, and the customer will be responsible for purchasing a new OQ service for such instrument. No refunds will be granted. Any damage to the instrument caused by such power disruption will be repaired at the customer's expense.

5.5. If a previously installed instrument does not meet the operational specifications or other requirements in this OQ Protocol, the customer is responsible for repairing the instrument, or having it repaired, at the customer's expense, except to the extent that the instrument and the required repairs are covered by an SCIEX warranty or service contract. If SCIEX execution of this OQ Protocol is interrupted by failure to meet such specification or other requirement, SCIEX may, at its option, terminate the execution of this OQ Protocol, and the customer will be responsible for purchasing a new OQ service for such instrument. No refunds will be granted.

6. Procedures for Execution

6.1. Each test is performed as described in the relevant sections.

6.2. Any discrepancies between the specified equipment parameters and those found on site must be identified as Exceptions or Failures.

6.2.1 If Exception, check "Yes" in the Exceptions field at the end of each verification section and explain the discrepancy in the Exception Report that is attached to the back of this OQ Protocol.

6.2.2 If Failure, document the failure information in the Comments section at the end of the verification section. Then, proceed directly to the OQ Completion Verification page to complete the final pages of the protocol.

6.3. Reporting Data

6.3.1 The completed OQ will consist of this OQ Protocol, duly signed by the appropriate persons, completed in clear handwriting and in ink, with appended documents as listed in the data sheet sections.

6.3.2 When each test or check is completed, the personnel performing the tests or checks shall initial, date, determine if the acceptance criteria are met, and attach indicated supporting documentation.

6.3.3 This OQ Protocol requires a reviewer's signature for each verification section and at the end of the report, indicating the satisfactory review and check of the report results.

6.3.4 The personnel performing and documenting this OQ Protocol should enter any comments regarding their findings in the relevant Comments section and indicate if an Exception exists for the Final Approver's attention. These comments may be continued in an appendix as necessary. Individual comments must be initialed and dated. The reviewers and approvers of the completed report can add their own initialed and dated responses to the comments, if desired.

6.3.5 All printouts and other supporting data must be cross-referenced to a specific test in this protocol, signed and dated, then attached to the back of this OQ Protocol. Attachments must include:

- On first and last page of each attachment:
 - Protocol Name
 - Protocol attachment number
 - Initials of tester
 - Date of test
 - Test No.
- On each page of the attachment
 - Pagination

7. System Description

7.1. The SYSTEM is a high performance bench top triple quadrupole mass spectrometer. It allows comprehensive analysis of biopharmaceutical compounds and it has the specificity needed for new drug development. For pharmaceutical and pharmacokinetic samples, MS/MS has the sensitivity and specificity needed to analyze hundreds of samples per day without requiring extensive sample preparation.

- The SYSTEM includes the following features:
- A compact design which allows stacking of LC equipment on top of the instrument
- Turbo V™ ion source, which allows for high flow rates
- Scanning in a mass range of m/z 50 to 2000
- Proven Curtain Gas™ supply barrier
- Higher sensitivity in all RF/DC scan modes
- QJet® ion guide that prefocuses the ions before they enter the vacuum chamber for higher sensitivity and signal-to-noise ratio
- Enhanced resolution at reduced scan speeds

8. Recommendations for Re-Qualification

8.1. SCIEX recommends that a SYSTEM OQ Protocol be performed to re-qualify the instrument after any of the following events:

8.1.1 After a major repair

8.1.2 After planned maintenance (PM)

8.2. An OQ can be performed to reverify the instrument per the customer's internal regulatory requirements.

8.3. SCIEX recommends annual qualification for all instruments.

IMPORTANT! SCIEX recommends that both the Installation Qualification (IQ) Protocol and the Operational Qualification (OQ) Protocol be executed any time the instrument is relocated or reinstalled.



9. Pre-Execution Verification

Before executing this OQ Protocol, complete the procedures in the following sections.

Section	Procedure	Description
9.1.	Field Service Training Verification	Verifies that the SCIEX FSE is certified to perform the OQ service on the SYSTEM.
9.2.	Customer Information	Records the customer information.
9.3.	Field Service Work Order Verification	Verifies that the field service work order for this OQ service has been created.
9.4.	Tools Verification	Records the tools used during the OQ protocol execution.
9.5.	Chemical Kit Verification	Records the chemical kit(s) used during the OQ protocol execution.

9.1. Field Service Training Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date										
9.1.1	Verify that the SCIEX FSE is identified and is certified to perform the OQ service on the SYSTEM.	The SCIEX FSE is identified and has applicable current certificates to complete this OQ Protocol.	<table border="1" data-bbox="1184 435 1759 721"> <thead> <tr> <th colspan="2">Field Service Employee</th> </tr> </thead> <tbody> <tr> <td>Name:</td> <td>Salvador Jodra Chuan/ Roberto San Millan</td> </tr> <tr> <td>Initials:</td> <td>SJC/RSM</td> </tr> <tr> <td>Employee #:</td> <td>104121/242823</td> </tr> <tr> <td>Certified?</td> <td><input checked="" type="checkbox"/> Yes / No</td> </tr> </tbody> </table> <p data-bbox="1234 802 1709 844">Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p data-bbox="1176 883 1772 935"><i>Attach a copy of the training certificate(s) to the back of this protocol.</i></p>	Field Service Employee		Name:	Salvador Jodra Chuan/ Roberto San Millan	Initials:	SJC/RSM	Employee #:	104121/242823	Certified?	<input checked="" type="checkbox"/> Yes / No	08-Julio-2024/ SJC
Field Service Employee														
Name:	Salvador Jodra Chuan/ Roberto San Millan													
Initials:	SJC/RSM													
Employee #:	104121/242823													
Certified?	<input checked="" type="checkbox"/> Yes / No													
Comments: N/A														
Were there exceptions? Yes / <input checked="" type="checkbox"/> No <i>(If Yes, complete the exception reports(s) and attach them to the back of this protocol.)</i>														
Reviewed By:				Date:										



9.2. Customer Information

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
9.2.1	Record the customer information.	The customer information is recorded.	<table border="1"><thead><tr><th colspan="2">Customer Information</th></tr></thead><tbody><tr><td>LCMS System ID:</td><td>11604</td></tr><tr><td>Laboratory ID:</td><td></td></tr><tr><td>Company Name:</td><td>SMART BIOANALYTIC</td></tr><tr><td>Company Address:</td><td>C/SANTIAGO GRISOLIA 2 TRES CANTOS,MADRID 28760</td></tr><tr><td>Contact Name:</td><td>ADAN ALPIZAR</td></tr></tbody></table>	Customer Information		LCMS System ID:	11604	Laboratory ID:		Company Name:	SMART BIOANALYTIC	Company Address:	C/SANTIAGO GRISOLIA 2 TRES CANTOS,MADRID 28760	Contact Name:	ADAN ALPIZAR	08-Julio-2024/ SJC
Customer Information																
LCMS System ID:	11604															
Laboratory ID:																
Company Name:	SMART BIOANALYTIC															
Company Address:	C/SANTIAGO GRISOLIA 2 TRES CANTOS,MADRID 28760															
Contact Name:	ADAN ALPIZAR															

Comments: N/A

Were there exceptions? Yes / No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)

Reviewed By:

Date:

9.3. Field Service Work Order Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date				
9.3.1	Verify that the field service work order for this OQ service has been created and properly recorded.	The field service work order is created and recorded.	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2" style="background-color: #cccccc;">Field Service Work Order</th> </tr> </thead> <tbody> <tr> <td style="width: 15%;">Number:</td> <td>01393576/01396652</td> </tr> </tbody> </table>	Field Service Work Order		Number:	01393576/01396652	09-julio-2024/ RSM
Field Service Work Order								
Number:	01393576/01396652							
Comments: N/A								
Were there exceptions? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)								
Reviewed By:				Date:				



9.4. Tools Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date														
9.4.1	Verify the service software tool used to execute this protocol.	<table border="1"> <tr> <th colspan="2" data-bbox="688 571 1159 685">Analyst Service Diagnostic (ASD) Software Tool</th> </tr> <tr> <td data-bbox="688 685 877 734">Version:</td> <td data-bbox="877 685 1159 734">≥ 3.5</td> </tr> <tr> <th colspan="2" data-bbox="688 734 1159 782">Tuning Tools</th> </tr> <tr> <td data-bbox="688 782 877 831">Version:</td> <td data-bbox="877 782 1159 831">≥ 2.10</td> </tr> </table>	Analyst Service Diagnostic (ASD) Software Tool		Version:	≥ 3.5	Tuning Tools		Version:	≥ 2.10	<table border="1"> <tr> <th colspan="2" data-bbox="1192 581 1759 652">Service Diagnostic Software Tool (Circle one:)</th> </tr> <tr> <td colspan="2" data-bbox="1192 652 1759 766" style="text-align: center;"> ASD Tuning Tools </td> </tr> <tr> <td data-bbox="1192 766 1381 815">Version:</td> <td data-bbox="1381 766 1759 815">3.5</td> </tr> </table> <p data-bbox="1243 938 1717 977">Circle One: Pass / Fail / Exception</p>	Service Diagnostic Software Tool (Circle one:)		ASD Tuning Tools		Version:	3.5	08-Julio-2024/ SJC
Analyst Service Diagnostic (ASD) Software Tool																		
Version:	≥ 3.5																	
Tuning Tools																		
Version:	≥ 2.10																	
Service Diagnostic Software Tool (Circle one:)																		
ASD Tuning Tools																		
Version:	3.5																	

9.4. Tools Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
9.4.2	Verify that the digital voltmeter calibration is valid.	The tool is identified, and the calibration is valid.	<table border="1"> <thead> <tr> <th colspan="2">Digital Voltmeter (DVM) Calibration</th> </tr> </thead> <tbody> <tr> <td>Manufacturer:</td> <td>Fluke</td> </tr> <tr> <td>Model Number:</td> <td>289</td> </tr> <tr> <td>Last Calibration Date:</td> <td>14-Mayo-2024</td> </tr> <tr> <td>Calibration Expiration Date:</td> <td>14-Mayo-2025</td> </tr> <tr> <td>Today's Date:</td> <td>08-Julio-2024</td> </tr> </tbody> </table> <p style="text-align: center;">Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p style="text-align: center;"><i>Attach a copy of the calibration certificate to the back of this protocol</i></p>	Digital Voltmeter (DVM) Calibration		Manufacturer:	Fluke	Model Number:	289	Last Calibration Date:	14-Mayo-2024	Calibration Expiration Date:	14-Mayo-2025	Today's Date:	08-Julio-2024	08-Julio-2024/ SJC
Digital Voltmeter (DVM) Calibration																
Manufacturer:	Fluke															
Model Number:	289															
Last Calibration Date:	14-Mayo-2024															
Calibration Expiration Date:	14-Mayo-2025															
Today's Date:	08-Julio-2024															
Comments: N/A																
Were there exceptions? Yes / <input checked="" type="checkbox"/> No <i>(If Yes, complete the exception reports(s) and attach them to the back of this protocol.)</i>																
Reviewed By:			Date:													



9.5. Chemical Kit Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																					
9.5.1	Identify and record the chemical kit used to perform operational verification tests. Verify the chemical kit has not expired	The chemical kit is identified and recorded. The chemical kit has not expired.	<table border="1"> <thead> <tr> <th colspan="3">Chemical Kit</th> </tr> <tr> <th></th> <th>Kit #1</th> <th>Kit #2</th> </tr> </thead> <tbody> <tr> <td>Part Number:</td> <td>4406127</td> <td>NA</td> </tr> <tr> <td>Description:</td> <td>Standards chemical kit with low/high concentration PPGs</td> <td>NA</td> </tr> <tr> <td>Lot number:</td> <td>M405197</td> <td>NA</td> </tr> <tr> <td>Expiration date:</td> <td>30-Junio-2025</td> <td>NA</td> </tr> <tr> <td>Today's Date:</td> <td>08-Julio-2024</td> <td>NA</td> </tr> </tbody> </table> <p style="text-align: center;">Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p style="text-align: center;"><i>Attach a copy of the certificate of analysis to the back of this protocol</i></p>	Chemical Kit				Kit #1	Kit #2	Part Number:	4406127	NA	Description:	Standards chemical kit with low/high concentration PPGs	NA	Lot number:	M405197	NA	Expiration date:	30-Junio-2025	NA	Today's Date:	08-Julio-2024	NA	08-Julio-2024/ SJC
Chemical Kit																									
	Kit #1	Kit #2																							
Part Number:	4406127	NA																							
Description:	Standards chemical kit with low/high concentration PPGs	NA																							
Lot number:	M405197	NA																							
Expiration date:	30-Junio-2025	NA																							
Today's Date:	08-Julio-2024	NA																							

Comments: N/A

Were there exceptions? Yes / No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)

Reviewed By:

Date:

10. Operational Qualification(“OQ”) Procedure

10.1. Summary of OQ Procedures

Operational Qualification includes the procedures in the sections indicated below.

Section	Procedure	Description
10.2.	System Hardware Identification	Identifies and records the system hardware on site.
10.3.	System Software Identification	Identifies and records the system software.
10.4.	System Maintenance Verification	Verifies that the SYSTEM is covered by a warranty or service contract, or that the user has a documented maintenance schedule and a record of maintenance.
10.5.	Power On, Electronic modules, and Voltage Verification	Verifies that the SYSTEM powers on properly, the instrument electronic modules function properly, and all tested voltages are within acceptable ranges.
10.6.	Operational Verification – Pre-Test Pressure Verification	Verifies that the SYSTEM vacuum pressures operate within specifications prior to chemical testing.
10.7.	Operational Verification – Chemical Tests – Triple Quadrupole	Verifies that the SYSTEM meets the operational specifications for peak intensity, peak width, mass shift and transmission efficiency for Triple Quadrupole functionality in positive, negative, and MRM modes.
10.8.	Operational Verification – Ion Source Tests	Verifies that the ion source meets operational specifications.
10.9.	Operational Verification – Post-Test Pressure Verification	Verifies that the SYSTEM vacuum pressures operate within specifications after completion of chemical testing.
10.10.	OQ Completion Verification	Verifies that the OQ has been executed, the OQ report has been written, and the OQ acceptance criteria have been met and/or exceptions have been recorded.



10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																		
10.2.1	Identify and record the SYSTEM hardware.	The SYSTEM hardware is identified and recorded.	<table border="1"><thead><tr><th colspan="2">SCIEX Triple Quad™ 4500 System</th></tr></thead><tbody><tr><td>Assembly number:</td><td>5020102</td></tr><tr><td>Serial number:</td><td>BJ21751305</td></tr><tr><td>Lab location:</td><td></td></tr></tbody></table> <table border="1"><thead><tr><th colspan="2">Roughing Pump</th></tr></thead><tbody><tr><td>Manufacturer:</td><td>Leybold</td></tr><tr><td>Model:</td><td>SV28BI</td></tr><tr><td>Assembly number:</td><td>960277v1705ES</td></tr><tr><td>Serial number:</td><td>31002122751</td></tr></tbody></table>	SCIEX Triple Quad™ 4500 System		Assembly number:	5020102	Serial number:	BJ21751305	Lab location:		Roughing Pump		Manufacturer:	Leybold	Model:	SV28BI	Assembly number:	960277v1705ES	Serial number:	31002122751	08-Julio-2024/ SJC
SCIEX Triple Quad™ 4500 System																						
Assembly number:	5020102																					
Serial number:	BJ21751305																					
Lab location:																						
Roughing Pump																						
Manufacturer:	Leybold																					
Model:	SV28BI																					
Assembly number:	960277v1705ES																					
Serial number:	31002122751																					

10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																								
10.2.1 <i>(cont'd)</i>	Identify and record the SYSTEM hardware.	The SYSTEM hardware is identified and recorded.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d3d3d3;"> <th colspan="2" style="text-align: center;">Acquisition Computer</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Sciex part number, if known</td> <td>5074486</td> </tr> <tr> <td>Computer Name:</td> <td>DESKTOP-STEDOID</td> </tr> <tr> <td>Domain Name:</td> <td>N/A</td> </tr> <tr> <td>Manufacturer:</td> <td>DELL</td> </tr> <tr> <td>Model:</td> <td>Alpha Workstation 2020</td> </tr> <tr> <td>Serial number:</td> <td>CF1DJ23</td> </tr> <tr> <td>Processor:</td> <td>Intel core i5-8500</td> </tr> <tr> <td>RAM</td> <td>32GB</td> </tr> <tr> <td>Hard drive (Partition 1) letter/size:</td> <td>C / 292GB</td> </tr> <tr> <td>Hard drive (Partition 2) letter/size:</td> <td>D / 1.01TB</td> </tr> <tr> <td>Hard drive (Partition 3) letter/size:</td> <td>V / 244GB</td> </tr> </tbody> </table>	Acquisition Computer		Sciex part number, if known	5074486	Computer Name:	DESKTOP-STEDOID	Domain Name:	N/A	Manufacturer:	DELL	Model:	Alpha Workstation 2020	Serial number:	CF1DJ23	Processor:	Intel core i5-8500	RAM	32GB	Hard drive (Partition 1) letter/size:	C / 292GB	Hard drive (Partition 2) letter/size:	D / 1.01TB	Hard drive (Partition 3) letter/size:	V / 244GB	08-Julio-2024/ SJC
Acquisition Computer																												
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																										
10.2.2	Identify and record the ion sources present for use with the SYSTEM.	The ion sources are identified and recorded.	<table border="1"> <thead> <tr> <th colspan="2">Ion Sources</th> </tr> <tr> <th colspan="2">Turbo V™ Ion Source</th> </tr> </thead> <tbody> <tr> <td>Serial number:</td> <td>27529130515</td> </tr> <tr> <td>Assembly number:</td> <td>1034049H</td> </tr> <tr> <th colspan="2">TurbolonSpray® probe</th> </tr> <tr> <td>Serial number:</td> <td>20084200611</td> </tr> <tr> <th colspan="2">APCI probe</th> </tr> <tr> <td>Serial number:</td> <td>20945200204</td> </tr> <tr> <th colspan="2">Other Optional Ion Sources</th> </tr> <tr> <th colspan="2">Optional Source #1</th> </tr> <tr> <td>Description:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> <tr> <td>Assembly Number:</td> <td>NA</td> </tr> <tr> <th colspan="2">Optional Source #2</th> </tr> <tr> <td>Description:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> <tr> <td>Assembly Number:</td> <td>NA</td> </tr> <tr> <th colspan="2">Optional Source #3</th> </tr> <tr> <td>Description:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> <tr> <td>Assembly Number:</td> <td>NA</td> </tr> </tbody> </table>	Ion Sources		Turbo V™ Ion Source		Serial number:	27529130515	Assembly number:	1034049H	TurbolonSpray® probe		Serial number:	20084200611	APCI probe		Serial number:	20945200204	Other Optional Ion Sources		Optional Source #1		Description:	NA	Serial number:	NA	Assembly Number:	NA	Optional Source #2		Description:	NA	Serial number:	NA	Assembly Number:	NA	Optional Source #3		Description:	NA	Serial number:	NA	Assembly Number:	NA	08-Julio-2024/ SJC
Ion Sources																																														
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																
10.2.3	Identify and record any optional equipment that is present for use with the SYSTEM.	Optional equipment is identified and recorded.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th colspan="2" style="text-align: center;">Gas Generator</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Manufacturer:</td> <td>NA</td> </tr> <tr> <td>Model:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th colspan="2" style="text-align: center;">Line Transformer #1</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Manufacturer:</td> <td>XENTER</td> </tr> <tr> <td>Model:</td> <td>TF 40/F</td> </tr> <tr> <td>Serial number:</td> <td>ETT.5422</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th colspan="2" style="text-align: center;">Line Transformer #2</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Manufacturer:</td> <td>NA</td> </tr> <tr> <td>Model:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th colspan="2" style="text-align: center;">Syringe Pump</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Manufacturer:</td> <td>NA</td> </tr> <tr> <td>Model:</td> <td>NA</td> </tr> <tr> <td>Serial number:</td> <td>NA</td> </tr> </tbody> </table>	Gas Generator		Manufacturer:	NA	Model:	NA	Serial number:	NA	Line Transformer #1		Manufacturer:	XENTER	Model:	TF 40/F	Serial number:	ETT.5422	Line Transformer #2		Manufacturer:	NA	Model:	NA	Serial number:	NA	Syringe Pump		Manufacturer:	NA	Model:	NA	Serial number:	NA	08-Julio-2024/ SJC
Gas Generator																																				
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																				
10.2.4	Identify and record any optional LC (Liquid Chromatography) system equipment that is present for use with the SYSTEM. Note: LC devices are only documented in this section and must be qualified separately.	Optional LC equipment is identified and recorded.	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="1184 449 1757 483">Optional LC Device 1</th> </tr> </thead> <tbody> <tr> <td data-bbox="1184 488 1440 542">Description:</td> <td data-bbox="1446 488 1757 542">Exion LC Reservoir Tray</td> </tr> <tr> <td data-bbox="1184 547 1440 600">Manufacturer:</td> <td data-bbox="1446 547 1757 600">Shimadzu</td> </tr> <tr> <td data-bbox="1184 605 1440 659">Model:</td> <td data-bbox="1446 605 1757 659">Exion LC Reservoir Tray</td> </tr> <tr> <td data-bbox="1184 664 1440 717">Serial number:</td> <td data-bbox="1446 664 1757 717">ABRES5905403</td> </tr> <tr> <td data-bbox="1184 722 1440 776">Firmware revision:</td> <td data-bbox="1446 722 1757 776">NA</td> </tr> <tr> <th colspan="2" data-bbox="1184 781 1757 815">Optional LC Device 2</th> </tr> <tr> <td data-bbox="1184 820 1440 873">Description:</td> <td data-bbox="1446 820 1757 873">Exion LC degasser</td> </tr> <tr> <td data-bbox="1184 878 1440 932">Manufacturer:</td> <td data-bbox="1446 878 1757 932">Shimadzu</td> </tr> <tr> <td data-bbox="1184 937 1440 990">Model:</td> <td data-bbox="1446 937 1757 990">Exion LC degasser</td> </tr> <tr> <td data-bbox="1184 995 1440 1049">Serial number:</td> <td data-bbox="1446 995 1757 1049">ABDG56075413</td> </tr> <tr> <td data-bbox="1184 1053 1440 1107">Firmware revision:</td> <td data-bbox="1446 1053 1757 1107">NA</td> </tr> <tr> <th colspan="2" data-bbox="1184 1112 1757 1146">Optional LC Device 3</th> </tr> <tr> <td data-bbox="1184 1151 1440 1205">Description:</td> <td data-bbox="1446 1151 1757 1205">Exion LC AD pump</td> </tr> <tr> <td data-bbox="1184 1209 1440 1263">Manufacturer:</td> <td data-bbox="1446 1209 1757 1263">Shimadzu</td> </tr> <tr> <td data-bbox="1184 1268 1440 1321">Model: Exion</td> <td data-bbox="1446 1268 1757 1321">Exion LC AD pump</td> </tr> <tr> <td data-bbox="1184 1326 1440 1380">Serial number:</td> <td data-bbox="1446 1326 1757 1380">AB3AD6077385</td> </tr> <tr> <td data-bbox="1184 1385 1440 1438">Firmware revision:</td> <td data-bbox="1446 1385 1757 1438">3.21</td> </tr> </tbody> </table>	Optional LC Device 1		Description:	Exion LC Reservoir Tray	Manufacturer:	Shimadzu	Model:	Exion LC Reservoir Tray	Serial number:	ABRES5905403	Firmware revision:	NA	Optional LC Device 2		Description:	Exion LC degasser	Manufacturer:	Shimadzu	Model:	Exion LC degasser	Serial number:	ABDG56075413	Firmware revision:	NA	Optional LC Device 3		Description:	Exion LC AD pump	Manufacturer:	Shimadzu	Model: Exion	Exion LC AD pump	Serial number:	AB3AD6077385	Firmware revision:	3.21	08-Julio-2024/ SJC
Optional LC Device 1																																								
Description:	Exion LC Reservoir Tray																																							
Manufacturer:	Shimadzu																																							
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																				
10.2.4 <i>(cont'd)</i>	Identify and record any optional LC (Liquid Chromatography) system equipment that is present for use with the SYSTEM. Note: LC devices are only documented in this section and should be qualified before use.	Optional LC equipment is identified and recorded.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e0e0e0;"> <th colspan="2" style="text-align: center;">Optional LC Device 4</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Description:</td> <td>Exion LC AD pump</td> </tr> <tr> <td>Manufacturer:</td> <td>Shimadzu</td> </tr> <tr> <td>Model:</td> <td>Exion LC AD pump</td> </tr> <tr> <td>Serial number:</td> <td>AB3AD6077384</td> </tr> <tr> <td>Firmware revision:</td> <td>3.21</td> </tr> <tr style="background-color: #e0e0e0;"> <th colspan="2" style="text-align: center;">Optional LC Device 5</th> </tr> <tr> <td>Description:</td> <td>Exion LC AD autosampler</td> </tr> <tr> <td>Manufacturer:</td> <td>Shimadzu</td> </tr> <tr> <td>Model:</td> <td>Exion LC AD autosampler</td> </tr> <tr> <td>Serial number:</td> <td>AB3AC6072889</td> </tr> <tr> <td>Firmware revision:</td> <td>3.23</td> </tr> <tr style="background-color: #e0e0e0;"> <th colspan="2" style="text-align: center;">Optional LC Device 6</th> </tr> <tr> <td>Description:</td> <td>Exion LC AC Column Oven</td> </tr> <tr> <td>Manufacturer:</td> <td>Shimadzu</td> </tr> <tr> <td>Model:</td> <td>Exion LC AC Column Oven</td> </tr> <tr> <td>Serial number:</td> <td>AB2CT6072545</td> </tr> <tr> <td>Firmware revision:</td> <td>2.1</td> </tr> </tbody> </table>	Optional LC Device 4		Description:	Exion LC AD pump	Manufacturer:	Shimadzu	Model:	Exion LC AD pump	Serial number:	AB3AD6077384	Firmware revision:	3.21	Optional LC Device 5		Description:	Exion LC AD autosampler	Manufacturer:	Shimadzu	Model:	Exion LC AD autosampler	Serial number:	AB3AC6072889	Firmware revision:	3.23	Optional LC Device 6		Description:	Exion LC AC Column Oven	Manufacturer:	Shimadzu	Model:	Exion LC AC Column Oven	Serial number:	AB2CT6072545	Firmware revision:	2.1	08-Julio-2024/ SJC
Optional LC Device 4																																								
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Description:	Exion LC AD autosampler																																							
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																				
10.2.4 (cont'd)	Identify and record any optional LC (Liquid Chromatography) system equipment that is present for use with the SYSTEM. Note: LC devices are only documented in this section and must be qualified separately.	Optional LC equipment is identified and recorded.	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="1184 449 1757 483">Optional LC Device 7</th> </tr> </thead> <tbody> <tr> <td data-bbox="1184 488 1440 542">Description:</td> <td data-bbox="1446 488 1757 542">Exion LC Solvent Valve</td> </tr> <tr> <td data-bbox="1184 547 1440 600">Manufacturer:</td> <td data-bbox="1446 547 1757 600">Shimadzu</td> </tr> <tr> <td data-bbox="1184 605 1440 659">Model:</td> <td data-bbox="1446 605 1757 659">Exion LC Solvent Valve</td> </tr> <tr> <td data-bbox="1184 664 1440 717">Serial number:</td> <td data-bbox="1446 664 1757 717">ABFCV5901718</td> </tr> <tr> <td data-bbox="1184 722 1440 776">Firmware revision:</td> <td data-bbox="1446 722 1757 776">NA</td> </tr> <tr> <th colspan="2" data-bbox="1184 781 1757 815">Optional LC Device 8</th> </tr> <tr> <td data-bbox="1184 820 1440 873">Description:</td> <td data-bbox="1446 820 1757 873">Exion LC System Controller</td> </tr> <tr> <td data-bbox="1184 878 1440 932">Manufacturer:</td> <td data-bbox="1446 878 1757 932">Shimadzu</td> </tr> <tr> <td data-bbox="1184 937 1440 990">Model:</td> <td data-bbox="1446 937 1757 990">Exion LC System Controller</td> </tr> <tr> <td data-bbox="1184 995 1440 1049">Serial number:</td> <td data-bbox="1446 995 1757 1049">ABCBM6074979</td> </tr> <tr> <td data-bbox="1184 1053 1440 1107">Firmware revision:</td> <td data-bbox="1446 1053 1757 1107">3.71</td> </tr> <tr> <th colspan="2" data-bbox="1184 1112 1757 1146">Optional LC Device 9</th> </tr> <tr> <td data-bbox="1184 1151 1440 1205">Description:</td> <td data-bbox="1446 1151 1757 1205">NA</td> </tr> <tr> <td data-bbox="1184 1209 1440 1263">Manufacturer:</td> <td data-bbox="1446 1209 1757 1263">NA</td> </tr> <tr> <td data-bbox="1184 1268 1440 1321">Model:</td> <td data-bbox="1446 1268 1757 1321">NA</td> </tr> <tr> <td data-bbox="1184 1326 1440 1380">Serial number:</td> <td data-bbox="1446 1326 1757 1380">NA</td> </tr> <tr> <td data-bbox="1184 1385 1440 1438">Firmware revision:</td> <td data-bbox="1446 1385 1757 1438">NA</td> </tr> </tbody> </table>	Optional LC Device 7		Description:	Exion LC Solvent Valve	Manufacturer:	Shimadzu	Model:	Exion LC Solvent Valve	Serial number:	ABFCV5901718	Firmware revision:	NA	Optional LC Device 8		Description:	Exion LC System Controller	Manufacturer:	Shimadzu	Model:	Exion LC System Controller	Serial number:	ABCBM6074979	Firmware revision:	3.71	Optional LC Device 9		Description:	NA	Manufacturer:	NA	Model:	NA	Serial number:	NA	Firmware revision:	NA	08-Julio-2024/ SJC
Optional LC Device 7																																								
Description:	Exion LC Solvent Valve																																							
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10.2. System Hardware Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
10.2.4 <i>(cont'd)</i>	Identify and record any optional LC (Liquid Chromatography) system equipment that is present for use with the SYSTEM. Note: LC devices are only documented in this section and must be qualified separately.	Optional LC equipment is identified and recorded.	<table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr style="background-color: #e0e0e0;"> <th colspan="2" style="text-align: center;">Optional LC Device 10</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Description:</td> <td style="padding: 2px;">NA</td> </tr> <tr> <td style="padding: 2px;">Manufacturer:</td> <td style="padding: 2px;">NA</td> </tr> <tr> <td style="padding: 2px;">Model:</td> <td style="padding: 2px;">NA</td> </tr> <tr> <td style="padding: 2px;">Serial number:</td> <td style="padding: 2px;">NA</td> </tr> <tr> <td style="padding: 2px;">Firmware revision:</td> <td style="padding: 2px;">NA</td> </tr> </tbody> </table>	Optional LC Device 10		Description:	NA	Manufacturer:	NA	Model:	NA	Serial number:	NA	Firmware revision:	NA	09-julio-2024/ RSM0
Optional LC Device 10																
Description:	NA															
Manufacturer:	NA															
Model:	NA															
Serial number:	NA															
Firmware revision:	NA															
Comments: N/A																
Were there exceptions? Yes / <input checked="" type="checkbox"/> No <i>(If Yes, complete the exception reports(s) and attach them to the back of this protocol.)</i>																
Reviewed By:			Date:													



10.3. System Software Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																										
10.3.1	<p>Record the software and firmware versions installed on the SYSTEM acquisition computer.</p> <p>Note: Software is only documented in this section and must be validated before use</p>	The installed software and firmware are recorded.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="background-color: #cccccc;">Computer Operating System</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Version:</td> <td>Windows 10 Enterprise LTSC 1809</td> </tr> <tr> <td>Service Pack:</td> <td>17763.2452</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="background-color: #cccccc;">System Acquisition Software</th> </tr> </thead> <tbody> <tr> <td>Name:</td> <td>Analyst</td> </tr> <tr> <td>Version:</td> <td>1.7</td> </tr> <tr> <td>Build:</td> <td>1.7.3.131</td> </tr> <tr> <td>Hotfix(es):</td> <td>NA</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="background-color: #cccccc;">Primary System Processing Software</th> </tr> </thead> <tbody> <tr> <td>Name:</td> <td>SCIEX OS</td> </tr> <tr> <td>Version:</td> <td>1.7</td> </tr> <tr> <td>Build:</td> <td>NA</td> </tr> <tr> <td>Hotfix(es):</td> <td>NA</td> </tr> </tbody> </table>	Computer Operating System		Version:	Windows 10 Enterprise LTSC 1809	Service Pack:	17763.2452	System Acquisition Software		Name:	Analyst	Version:	1.7	Build:	1.7.3.131	Hotfix(es):	NA	Primary System Processing Software		Name:	SCIEX OS	Version:	1.7	Build:	NA	Hotfix(es):	NA	<p>08-Julio-2024/ SJC</p>
Computer Operating System																														
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10.3. System Software Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																										
10.3.1 (cont'd)	Record the software and firmware versions installed on the SYSTEM acquisition computer.	The installed software and firmware are recorded.	<table border="1"> <thead> <tr> <th colspan="2">Optional System Software 1</th> </tr> </thead> <tbody> <tr> <td>Name:</td> <td>NA</td> </tr> <tr> <td>Version:</td> <td>NA</td> </tr> <tr> <td>Build:</td> <td>NA</td> </tr> <tr> <td>Hotfix(es):</td> <td>NA</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="2">Optional System Software 2</th> </tr> </thead> <tbody> <tr> <td>Name:</td> <td>NA</td> </tr> <tr> <td>Version:</td> <td>NA</td> </tr> <tr> <td>Build:</td> <td>NA</td> </tr> <tr> <td>Hotfix(es):</td> <td>NA</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="2">Optional LC Driver Software</th> </tr> </thead> <tbody> <tr> <td>Manufacturer:</td> <td>NA</td> </tr> <tr> <td>Version:</td> <td>NA</td> </tr> </tbody> </table>	Optional System Software 1		Name:	NA	Version:	NA	Build:	NA	Hotfix(es):	NA	Optional System Software 2		Name:	NA	Version:	NA	Build:	NA	Hotfix(es):	NA	Optional LC Driver Software		Manufacturer:	NA	Version:	NA	08-Julio-2024/ SJC
Optional System Software 1																														
Name:	NA																													
Version:	NA																													
Build:	NA																													
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Optional LC Driver Software																														
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10.3. System Software Identification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date						
10.3.1 (cont'd)	Record the software and firmware versions installed on the SYSTEM acquisition computer.	The installed software and firmware are recorded.	<table border="1"><thead><tr><th colspan="2">Instrument Firmware</th></tr></thead><tbody><tr><td>ICB Main Code:</td><td>PIL1901</td></tr><tr><td>Configuration Header:</td><td>TripleQuad4500 170908 20 A1 D5115761C</td></tr></tbody></table>	Instrument Firmware		ICB Main Code:	PIL1901	Configuration Header:	TripleQuad4500 170908 20 A1 D5115761C	08-Julio-2024/ SJC
Instrument Firmware										
ICB Main Code:	PIL1901									
Configuration Header:	TripleQuad4500 170908 20 A1 D5115761C									

Comments: N/A

Were there exceptions? Yes / No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)

Reviewed By:

Date:

10.4. System Maintenance Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date										
10.4.1	Verify that the SYSTEM is covered by a warranty or service contract and/or customer documented maintenance schedule. Note: Some service contract types do not include scheduled maintenance.	The system is under warranty or contract and/or the customer has a documented maintenance schedule or SOP.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">Warranty or Service Contract</th> </tr> </thead> <tbody> <tr> <td style="width: 60%;">Expiration date:</td> <td style="text-align: center;">29-Junio-2025</td> </tr> <tr> <td>Service Contract or Warranty number:</td> <td style="text-align: center;">S40517798</td> </tr> <tr> <td>Maintenance schedule or SOP:</td> <td style="text-align: center;">Julio-2024</td> </tr> <tr> <td>Planned service or user maintenance due date:</td> <td style="text-align: center;">Julio-2024</td> </tr> </tbody> </table> <p style="text-align: center; font-weight: bold;">Circle One <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p style="text-align: center; font-style: italic;">If applicable, attach a copy of the warranty terms and conditions or service contract to the back of this protocol.</p>	Warranty or Service Contract		Expiration date:	29-Junio-2025	Service Contract or Warranty number:	S40517798	Maintenance schedule or SOP:	Julio-2024	Planned service or user maintenance due date:	Julio-2024	08-Julio-2024/ SJC0
Warranty or Service Contract														
Expiration date:	29-Junio-2025													
Service Contract or Warranty number:	S40517798													
Maintenance schedule or SOP:	Julio-2024													
Planned service or user maintenance due date:	Julio-2024													
Note: SCIEX does not endorse the suitability of any proposed maintenance plan or schedule that is not provided by SCIEX. Customers should record all instrument maintenance activities for future reference.														
Comments: N/A														
Were there exceptions? Yes / <input checked="" type="checkbox"/> No (If Yes, attach the exception report(s) to the back of this protocol.)														
Reviewed By:				Date:										



10.5. Power On, Electronic Modules, and Voltage Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																		
10.5.1	Verify that the instrument powers on properly and the instrument electronic modules function properly.	<p>After turning the power on, LEDs on the front cover will light up as follows:</p> <ul style="list-style-type: none"> • After the instrument is turned on, all five LEDs are lit. • The power LED remains lit while the other four LEDs will flash for two seconds and then turn off. • The vacuum LED will then start flashing. • After the proper vacuum has been achieved the vacuum LED remains lit. 	<p>Circle One: Pass / Fail / Exception</p>	08-Julio-2024/ SJC																		
10.5.2	Measure the RF tuning voltages for Q1 and Q3 Coil Boxes at the 2000 amu preset park mass, and record the results.	<table border="1"> <thead> <tr> <th colspan="3">RF Tuning Voltage Criteria</th> </tr> <tr> <th>Park Mass (2000amu)</th> <th>Q1 Coil Box (V)</th> <th>Q3 Coil Box (V)</th> </tr> </thead> <tbody> <tr> <td>Min</td> <td>1.200</td> <td>1.450</td> </tr> <tr> <td>Max</td> <td>2.450</td> <td>2.050</td> </tr> </tbody> </table>	RF Tuning Voltage Criteria			Park Mass (2000amu)	Q1 Coil Box (V)	Q3 Coil Box (V)	Min	1.200	1.450	Max	2.450	2.050	<table border="1"> <thead> <tr> <th colspan="2">RF Tuning Voltage Results</th> </tr> </thead> <tbody> <tr> <td>Q1 Coil Box Voltage</td> <td>1.74 V</td> </tr> <tr> <td>Q3 Coil Box Voltage</td> <td>1.67 V</td> </tr> </tbody> </table> <p>Circle One: Pass / Fail / Exception</p>	RF Tuning Voltage Results		Q1 Coil Box Voltage	1.74 V	Q3 Coil Box Voltage	1.67 V	08-Julio-2024/ SJC
RF Tuning Voltage Criteria																						
Park Mass (2000amu)	Q1 Coil Box (V)	Q3 Coil Box (V)																				
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10.5. Power On, Electronic Modules, and Voltage Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																
10.5.3	Using the service software tool set the Qjet voltage at the 50 and 200 amu and record the results.	<table border="1"> <thead> <tr> <th colspan="2">Qjet Voltages Criteria</th> </tr> <tr> <th>Qjet Voltage (VDC)</th> <th>Value in DVM (VDC)</th> </tr> </thead> <tbody> <tr> <td>50</td> <td>$0.085 \leq QJ_{50} \leq 0.15$</td> </tr> <tr> <td>200</td> <td>$0.10 \leq QJ_{200} \leq 0.20$</td> </tr> </tbody> </table>	Qjet Voltages Criteria		Qjet Voltage (VDC)	Value in DVM (VDC)	50	$0.085 \leq QJ_{50} \leq 0.15$	200	$0.10 \leq QJ_{200} \leq 0.20$	<table border="1"> <thead> <tr> <th colspan="2">Qjet Voltages</th> </tr> <tr> <th>Qjet Voltage (VDC)</th> <th>Value in DVM (VDC)</th> </tr> </thead> <tbody> <tr> <td>50</td> <td>0.10 V</td> </tr> <tr> <td>200</td> <td>0.14 v</td> </tr> </tbody> </table> <p>Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p>	Qjet Voltages		Qjet Voltage (VDC)	Value in DVM (VDC)	50	0.10 V	200	0.14 v	08-Julio-2024/ SJC
Qjet Voltages Criteria																				
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Qjet Voltages																				
Qjet Voltage (VDC)	Value in DVM (VDC)																			
50	0.10 V																			
200	0.14 v																			





10.5. Power On, Electronic Modules, and Voltage Verification

Test No.	Test Procedure	Acceptance Criteria			Actual Results			Initials / Date																																																																										
10.5.4	Verify that the lens power supply voltages are within their acceptable ranges using the service software tool.	<table border="1"> <thead> <tr> <th>Ion Optics Element Description</th> <th>Set Voltages (Max/Min)</th> <th>Voltage Acceptable Range</th> </tr> </thead> <tbody> <tr><td>Orifice (DP)</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>QJet®</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Entrance Potential (Q0)</td><td>±35.0 V</td><td>±2.5 V</td></tr> <tr><td>Interquad Lens 1 (IQ1)</td><td>±40.0 V</td><td>±2.5 V</td></tr> <tr><td>Stubby 1 (ST1)</td><td>±40.0 V</td><td>±2.5 V</td></tr> <tr><td>Stubby 2 (ST2)</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Q2 LINAC</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Q2 Rod Offset (RO2)</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Interquad Lens 3 (IQ3)</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Stubby 3 (ST3)</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Exit Lens</td><td>±300 V</td><td>±10 V</td></tr> <tr><td>Deflector (DEFL)</td><td>±300 V</td><td>±10 V</td></tr> </tbody> </table>	Ion Optics Element Description	Set Voltages (Max/Min)	Voltage Acceptable Range	Orifice (DP)	±300 V	±10 V	QJet®	±300 V	±10 V	Entrance Potential (Q0)	±35.0 V	±2.5 V	Interquad Lens 1 (IQ1)	±40.0 V	±2.5 V	Stubby 1 (ST1)	±40.0 V	±2.5 V	Stubby 2 (ST2)	±300 V	±10 V	Q2 LINAC	±300 V	±10 V	Q2 Rod Offset (RO2)	±300 V	±10 V	Interquad Lens 3 (IQ3)	±300 V	±10 V	Stubby 3 (ST3)	±300 V	±10 V	Exit Lens	±300 V	±10 V	Deflector (DEFL)	±300 V	±10 V	<table border="1"> <thead> <tr> <th>Ion Optics Element Description</th> <th colspan="2">Readings (VDC)</th> </tr> </thead> <tbody> <tr><td>Orifice (DP)</td><td>+300.7V</td><td>-300.7V</td></tr> <tr><td>QJet®</td><td>+299V</td><td>-299V</td></tr> <tr><td>Entrance Potential (Q0)</td><td>+34.8V</td><td>-34.8V</td></tr> <tr><td>Interquad Lens 1 (IQ1)</td><td>+39.7V</td><td>-39.1V</td></tr> <tr><td>Stubby 1 (ST1)</td><td>+39.7V</td><td>-39.1V</td></tr> <tr><td>Stubby 2 (ST2)</td><td>+300.2V</td><td>-300.7V</td></tr> <tr><td>Q2 LINAC</td><td>+300.3V</td><td>-300.3V</td></tr> <tr><td>Q2 Rod Offset (RO2)</td><td>+300.3V</td><td>-300.3V</td></tr> <tr><td>Interquad Lens 3 (IQ3)</td><td>+300.2V</td><td>-300.7V</td></tr> <tr><td>Stubby 3 (ST3)</td><td>+300.1V</td><td>-300.7V</td></tr> <tr><td>Exit Lens</td><td>+300.2V</td><td>-300.7V</td></tr> <tr><td>Deflector (DF)</td><td>+300.4V</td><td>-300.7V</td></tr> </tbody> </table>	Ion Optics Element Description	Readings (VDC)		Orifice (DP)	+300.7V	-300.7V	QJet®	+299V	-299V	Entrance Potential (Q0)	+34.8V	-34.8V	Interquad Lens 1 (IQ1)	+39.7V	-39.1V	Stubby 1 (ST1)	+39.7V	-39.1V	Stubby 2 (ST2)	+300.2V	-300.7V	Q2 LINAC	+300.3V	-300.3V	Q2 Rod Offset (RO2)	+300.3V	-300.3V	Interquad Lens 3 (IQ3)	+300.2V	-300.7V	Stubby 3 (ST3)	+300.1V	-300.7V	Exit Lens	+300.2V	-300.7V	Deflector (DF)	+300.4V	-300.7V	08-Julio-2024/ SJC
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<p>Circle One: Pass / Fail / Exception</p>																																																																																		

10.5. Power On, Electronic Modules, and Voltage Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date
10.5.5	Perform the high pressure source and blocked exhaust flow tests.	High Pressure source and blocked exhaust flow tests complete successfully.	Circle One: <input checked="" type="radio"/> Pass / Fail / Exception	09-julio-2024/ RSM
Comments: N/A				
Were there exceptions? Yes / <input checked="" type="radio"/> No <i>(If Yes, attach the exception report(s) to the back of this protocol.)</i>				
Reviewed By:			Date:	



10.6. Operational Verification – Pre-Test Pressure Verification

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
10.6.1	Verify the pre-test vacuum pressure of the instrument.	Pre-test pressure in the vacuum chamber is as follows: <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>CAD Gas Setting</th> <th>Vacuum Chamber Pressure</th> </tr> </thead> <tbody> <tr> <td>Zero (Off)</td> <td>$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD0}} \leq 1.1 \times 10^{-5} \text{ torr}$</td> </tr> <tr> <td>12 (Full)</td> <td>$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD12}} - P_{\text{CAD0}} \leq 2.8 \times 10^{-5} \text{ torr}$</td> </tr> </tbody> </table>	CAD Gas Setting	Vacuum Chamber Pressure	Zero (Off)	$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD0}} \leq 1.1 \times 10^{-5} \text{ torr}$	12 (Full)	$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD12}} - P_{\text{CAD0}} \leq 2.8 \times 10^{-5} \text{ torr}$	Pre-test pressure in the vacuum chamber is as follows: <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>CAD Gas Setting</th> <th>Vacuum Chamber Pressure</th> </tr> </thead> <tbody> <tr> <td>Zero (Off)</td> <td>0.46 E-5 TORR</td> </tr> <tr> <td>12 (Full)</td> <td>2.3 E-5 TORR</td> </tr> </tbody> </table> <p style="text-align: center;">Circle One: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail / Exception</p>	CAD Gas Setting	Vacuum Chamber Pressure	Zero (Off)	0.46 E-5 TORR	12 (Full)	2.3 E-5 TORR	09-julio-2024/ RSM
CAD Gas Setting	Vacuum Chamber Pressure															
Zero (Off)	$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD0}} \leq 1.1 \times 10^{-5} \text{ torr}$															
12 (Full)	$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD12}} - P_{\text{CAD0}} \leq 2.8 \times 10^{-5} \text{ torr}$															
CAD Gas Setting	Vacuum Chamber Pressure															
Zero (Off)	0.46 E-5 TORR															
12 (Full)	2.3 E-5 TORR															

Comments: N/A

Were there exceptions? Yes / No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)

Reviewed By:

Date:

10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																		
10.7.1	<p>Verify performance of the quadrupole 1 rod set (Q1) in positive ion mode by running the Q1 Positive PPG test.</p> <p>Test solution: PPG 2x10⁻⁶ M</p> <p>Flow Rate: 5 µl/min</p>	<p>Verification: Q1 Positive Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q1+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Specification</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>≥ 8.0 × 10⁶</td> </tr> <tr> <td>500.380</td> <td>≥ 8.0 × 10⁶</td> </tr> <tr> <td>906.673</td> <td>≥ 2.0 × 10⁷</td> </tr> <tr> <td>1952.427</td> <td>≥ 8.8 × 10⁵</td> </tr> </tbody> </table> <p>Verification: Q1 Positive Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q1+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Specification</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>500.380</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>906.673</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>1952.427</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Q1+; 10 Da/s; 10 MCA or Σ		Mass (Da)	Specification	Intensity (cps)	175.133	≥ 8.0 × 10 ⁶	500.380	≥ 8.0 × 10 ⁶	906.673	≥ 2.0 × 10 ⁷	1952.427	≥ 8.8 × 10 ⁵	Q1+; 10 Da/s; 10 MCA or Σ			Mass (Da)	Specification		Peak width (Da)	Δ Mass (Da)	175.133	0.6 to 0.8	≤ 0.1	500.380	0.6 to 0.8	≤ 0.1	906.673	0.6 to 0.8	≤ 0.1	1952.427	0.6 to 0.8	≤ 0.1	<p>Verification: Q1 Positive Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q1+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Results</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>2.2423e7</td> </tr> <tr> <td>500.380</td> <td>3.0858e7</td> </tr> <tr> <td>906.673</td> <td>3.7462e7</td> </tr> <tr> <td>1952.427</td> <td>7.8233e6</td> </tr> </tbody> </table> <p>Verification: Q1 Positive Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q1+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Results</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>0.7129</td> <td>-0.0170</td> </tr> <tr> <td>500.380</td> <td>0.6927</td> <td>0.0111</td> </tr> <tr> <td>906.673</td> <td>0.6905</td> <td>0.0200</td> </tr> <tr> <td>1952.427</td> <td>0.7517</td> <td>0.0768</td> </tr> </tbody> </table>	Q1+; 10 Da/s; 10 MCA or Σ		Mass (Da)	Results	Intensity (cps)	175.133	2.2423e7	500.380	3.0858e7	906.673	3.7462e7	1952.427	7.8233e6	Q1+; 10 Da/s; 10 MCA or Σ			Mass (Da)	Results		Peak width (Da)	Δ Mass (Da)	175.133	0.7129	-0.0170	500.380	0.6927	0.0111	906.673	0.6905	0.0200	1952.427	0.7517	0.0768	09-julio-2024/ RSM
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500.380	0.6927	0.0111																																																																				
906.673	0.6905	0.0200																																																																				
1952.427	0.7517	0.0768																																																																				





10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																																																		
10.7.1 (cont'd)	Verify the peak width for the identified masses. In the Actual Results column, circle "Y" if the peak width meets the specification or "N" otherwise.	Q1+; Peak width (Da) for identified masses: <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr><td>59.050</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>175.133</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>500.380</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>616.464</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>906.673</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>1254.925</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>1545.134</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> <tr><td>1952.427</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td><td>0.6 to 0.8</td></tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	175.133	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	500.380	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	616.464	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	906.673	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1254.925	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1545.134	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1952.427	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	Verify that the specification was met by circling the results for each peak. Recording the actual peak width is not required. <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr><td>59.050</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>175.133</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>500.380</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>616.464</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>906.673</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>1254.925</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>1545.134</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> <tr><td>1952.427</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td><td><input checked="" type="checkbox"/> Y / N</td></tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	<input checked="" type="checkbox"/> Y / N	175.133	<input checked="" type="checkbox"/> Y / N	500.380	<input checked="" type="checkbox"/> Y / N	616.464	<input checked="" type="checkbox"/> Y / N	906.673	<input checked="" type="checkbox"/> Y / N	1254.925	<input checked="" type="checkbox"/> Y / N	1545.134	<input checked="" type="checkbox"/> Y / N	1952.427	<input checked="" type="checkbox"/> Y / N	09-julio-2024/ RSM																								
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																																																		
10.7.1 (cont'd)	Verify the mass shift result for the identified masses. In the Actual Results column, circle "Y" if the peak width meets the specification or "N" otherwise.	<p>Q1+; mass shift (Δ Mass) for identified masses:</p> <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>175.133</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>500.380</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>616.464</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>906.673</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1254.925</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1545.134</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1952.427</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	175.133	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	500.380	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	616.464	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	906.673	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1254.925	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1545.134	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1952.427	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	<p>Verify that the specification was met by circling the results for each peak. Recording the actual peak width is not required.</p> <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>175.133</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>500.380</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>616.464</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>906.673</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1254.925</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1545.134</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1952.427</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> </tbody> </table> <p>Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p><i>Attach printouts of spectra, with peak intensities, peak width, and mass shift results, complete with the method file information, to the back of this protocol</i></p>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	<input checked="" type="checkbox"/> /N	175.133	<input checked="" type="checkbox"/> /N	500.380	<input checked="" type="checkbox"/> /N	616.464	<input checked="" type="checkbox"/> /N	906.673	<input checked="" type="checkbox"/> /N	1254.925	<input checked="" type="checkbox"/> /N	1545.134	<input checked="" type="checkbox"/> /N	1952.427	<input checked="" type="checkbox"/> /N	09-julio-2024/ RSM																								
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																		
10.7.2	Verify performance of the quadrupole 3 rod set (Q3) in positive ion mode by running the Q3 Positive PPG test. Test solution: PPG 2x10 ⁻⁶ M Flow Rate: 5 µl/min	Verification: Q3 Positive Mode <table border="1"> <thead> <tr> <th colspan="2">Q3+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Specification</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>≥ 8.0 × 10⁶</td> </tr> <tr> <td>500.380</td> <td>≥ 8.0 × 10⁶</td> </tr> <tr> <td>906.673</td> <td>≥ 2.0 × 10⁷</td> </tr> <tr> <td>1952.427</td> <td>≥ 8.8 × 10⁵</td> </tr> </tbody> </table> Verification: Q3 Positive Mode <table border="1"> <thead> <tr> <th colspan="3">Q3+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Specification</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>500.380</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>906.673</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>1952.427</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Q3+; 10 Da/s; 10 MCA or Σ		Mass (Da)	Specification	Intensity (cps)	175.133	≥ 8.0 × 10 ⁶	500.380	≥ 8.0 × 10 ⁶	906.673	≥ 2.0 × 10 ⁷	1952.427	≥ 8.8 × 10 ⁵	Q3+; 10 Da/s; 10 MCA or Σ			Mass (Da)	Specification		Peak width (Da)	Δ Mass (Da)	175.133	0.6 to 0.8	≤ 0.1	500.380	0.6 to 0.8	≤ 0.1	906.673	0.6 to 0.8	≤ 0.1	1952.427	0.6 to 0.8	≤ 0.1	Verification: Q3 Positive Mode <table border="1"> <thead> <tr> <th colspan="2">Q3+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Results</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>2.0359e7</td> </tr> <tr> <td>500.380</td> <td>2.5199e7</td> </tr> <tr> <td>906.673</td> <td>3.5357e7</td> </tr> <tr> <td>1952.427</td> <td>3.1956e6</td> </tr> </tbody> </table> Verification: Q3 Positive Mode <table border="1"> <thead> <tr> <th colspan="3">Q3+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Results</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>175.133</td> <td>0.7802</td> <td>0.0110</td> </tr> <tr> <td>500.380</td> <td>0.7076</td> <td>-5.6622e-3</td> </tr> <tr> <td>906.673</td> <td>0.7891</td> <td>8.7407e-3</td> </tr> <tr> <td>1952.427</td> <td>0.6826</td> <td>0.0228</td> </tr> </tbody> </table>	Q3+; 10 Da/s; 10 MCA or Σ		Mass (Da)	Results	Intensity (cps)	175.133	2.0359e7	500.380	2.5199e7	906.673	3.5357e7	1952.427	3.1956e6	Q3+; 10 Da/s; 10 MCA or Σ			Mass (Da)	Results		Peak width (Da)	Δ Mass (Da)	175.133	0.7802	0.0110	500.380	0.7076	-5.6622e-3	906.673	0.7891	8.7407e-3	1952.427	0.6826	0.0228	09-julio-2024/ RSM
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906.673	0.7891	8.7407e-3																																																																				
1952.427	0.6826	0.0228																																																																				

10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

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10.7.2 (cont'd)	Verify the peak width for the identified masses. In the Actual Results column, circle "Y" if the peak width meets the specification or "N" otherwise.	Q3+; Peak width (Da) for identified masses: <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>175.133</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>500.380</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>616.464</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>906.673</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>1254.925</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>1545.134</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> <tr> <td>1952.427</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> <td>0.6 to 0.8</td> </tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	175.133	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	500.380	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	616.464	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	906.673	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1254.925	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1545.134	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	1952.427	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	0.6 to 0.8	Verify that the specification was met by circling the results for each peak. Recording the actual peak width is not required. <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>175.133</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>500.380</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>616.464</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>906.673</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1254.925</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1545.134</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1952.427</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	<input checked="" type="checkbox"/> /N	175.133	<input checked="" type="checkbox"/> /N	500.380	<input checked="" type="checkbox"/> /N	616.464	<input checked="" type="checkbox"/> /N	906.673	<input checked="" type="checkbox"/> /N	1254.925	<input checked="" type="checkbox"/> /N	1545.134	<input checked="" type="checkbox"/> /N	1952.427	<input checked="" type="checkbox"/> /N	09-julio-2024/ RSM																								
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																																																		
10.7.2 (cont'd)	Verify the mass shift result for the identified masses. In the Actual Results column, circle "Y" if the peak width meets the specification or "N" otherwise.	<p>Q3+; mass shift (Δ Mass) for identified masses:</p> <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>175.133</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>500.380</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>616.464</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>906.673</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1254.925</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1545.134</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> <tr> <td>1952.427</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	175.133	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	500.380	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	616.464	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	906.673	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1254.925	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1545.134	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	1952.427	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	<p>Verify that the specification was met by circling the results for each peak. Recording the actual peak width is not required.</p> <table border="1"> <thead> <tr> <th rowspan="2">Mass (Da)</th> <th>10 Da/s</th> <th>200 Da/s</th> <th>1000 Da/s</th> <th>2000 Da/s</th> </tr> <tr> <th>10 MCA or Σ</th> <th>50 MCA or Σ</th> <th>50 MCA or Σ</th> <th>100 MCA or Σ</th> </tr> </thead> <tbody> <tr> <td>59.050</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>175.133</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>500.380</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>616.464</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>906.673</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1254.925</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1545.134</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> <tr> <td>1952.427</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> <td><input checked="" type="checkbox"/>/N</td> </tr> </tbody> </table> <p>Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p>Attach printouts of spectra, with peak intensities, peak width, and mass shift results, complete with the method file information, to the back of this protocol</p>	Mass (Da)	10 Da/s	200 Da/s	1000 Da/s	2000 Da/s	10 MCA or Σ	50 MCA or Σ	50 MCA or Σ	100 MCA or Σ	59.050	<input checked="" type="checkbox"/> /N	175.133	<input checked="" type="checkbox"/> /N	500.380	<input checked="" type="checkbox"/> /N	616.464	<input checked="" type="checkbox"/> /N	906.673	<input checked="" type="checkbox"/> /N	1254.925	<input checked="" type="checkbox"/> /N	1545.134	<input checked="" type="checkbox"/> /N	1952.427	<input checked="" type="checkbox"/> /N	09-julio-2024/ RSM																								
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																														
10.7.3	<p>Verify performance of the quadrupole 1 rod set (Q1) in negative ion mode by running the Q1 Negative PPG test.</p> <p>Test solution: PPG 3x10⁻⁴ M</p> <p>Flow Rate: 10 µl/min</p>	<p>Verification: Q1 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q1-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Specification</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>≥ 1.8 × 10⁷</td> </tr> <tr> <td>1863.306</td> <td>≥ 1.4 × 10⁶</td> </tr> </tbody> </table> <p>Verification: Q1 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q1-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Specification</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>1863.306</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Q1-; 10 Da/s; 10 MCA or Σ		Mass (Da)	Specification	Intensity (cps)	933.636	≥ 1.8 × 10 ⁷	1863.306	≥ 1.4 × 10 ⁶	Q1-; 10 Da/s; 10 MCA or Σ			Mass (Da)	Specification		Peak width (Da)	Δ Mass (Da)	933.636	0.6 to 0.8	≤ 0.1	1863.306	0.6 to 0.8	≤ 0.1	<p>Verification: Q1 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q1-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Results</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>2.9149e7</td> </tr> <tr> <td>1863.306</td> <td>4.4863e6</td> </tr> </tbody> </table> <p>Verification: Q1 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q1-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Results</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>0.6994</td> <td>3.4996e-3</td> </tr> <tr> <td>1863.306</td> <td>0.6740</td> <td>0.0256</td> </tr> </tbody> </table>	Q1-; 10 Da/s; 10 MCA or Σ		Mass (Da)	Results	Intensity (cps)	933.636	2.9149e7	1863.306	4.4863e6	Q1-; 10 Da/s; 10 MCA or Σ			Mass (Da)	Results		Peak width (Da)	Δ Mass (Da)	933.636	0.6994	3.4996e-3	1863.306	0.6740	0.0256	09-julio-2024/ RSM
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

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10.7.4	<p>Verify performance of the quadrupole 3 rod set (Q3) in negative ion mode by running the Q3 Negative PPG test.</p> <p>Test solution: PPG 3x10⁻⁴ M</p> <p>Flow Rate: 10 µl/min</p>	<p>Verification: Q3 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q3-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Specification</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>$\geq 1.8 \times 10^7$</td> </tr> <tr> <td>1863.306</td> <td>$\geq 2.0 \times 10^6$</td> </tr> </tbody> </table> <p>Verification: Q3 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q3-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Specification</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> <tr> <td>1863.306</td> <td>0.6 to 0.8</td> <td>≤ 0.1</td> </tr> </tbody> </table>	Q3-; 10 Da/s; 10 MCA or Σ		Mass (Da)	Specification	Intensity (cps)	933.636	$\geq 1.8 \times 10^7$	1863.306	$\geq 2.0 \times 10^6$	Q3-; 10 Da/s; 10 MCA or Σ			Mass (Da)	Specification		Peak width (Da)	Δ Mass (Da)	933.636	0.6 to 0.8	≤ 0.1	1863.306	0.6 to 0.8	≤ 0.1	<p>Verification: Q3 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="2">Q3-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th>Results</th> </tr> <tr> <th>Intensity (cps)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>2.3482e7</td> </tr> <tr> <td>1863.306</td> <td>2.3831e6</td> </tr> </tbody> </table> <p>Verification: Q1 Negative Mode</p> <table border="1"> <thead> <tr> <th colspan="3">Q3-; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th rowspan="2">Mass (Da)</th> <th colspan="2">Results</th> </tr> <tr> <th>Peak width (Da)</th> <th>Δ Mass (Da)</th> </tr> </thead> <tbody> <tr> <td>933.636</td> <td>0.7433</td> <td>0.0137</td> </tr> <tr> <td>1863.306</td> <td>0.7263</td> <td>0.0224</td> </tr> </tbody> </table>	Q3-; 10 Da/s; 10 MCA or Σ		Mass (Da)	Results	Intensity (cps)	933.636	2.3482e7	1863.306	2.3831e6	Q3-; 10 Da/s; 10 MCA or Σ			Mass (Da)	Results		Peak width (Da)	Δ Mass (Da)	933.636	0.7433	0.0137	1863.306	0.7263	0.0224	09-julio-2024/ RSM
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

9.1.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																																																																																																		
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10.7. Operational Verification – Chemical Tests – Triple Quadrupole

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date								
10.7.5	<p>Verify MS₁/MS₂ performance by running the reserpine MS/MS test.</p> <p>Test solution: Reserpine solution 0.167 pmol/μL</p> <p>Flow Rate: 5 μl/min</p>	<table border="1"> <thead> <tr> <th colspan="2">Q1+ and MS2+; 10 Da/s; 10 MCA or Σ</th> </tr> <tr> <th>Test Item</th> <th>Specification</th> </tr> </thead> <tbody> <tr> <td> $\frac{\text{Intensity of 195.1}}{\text{Intensity of 609.3 (or as calibrated)}} \times 100$ </td> <td>≥ 10%</td> </tr> </tbody> </table>	Q1+ and MS2+; 10 Da/s; 10 MCA or Σ		Test Item	Specification	$\frac{\text{Intensity of 195.1}}{\text{Intensity of 609.3 (or as calibrated)}} \times 100$	≥ 10%	<table border="1"> <tr> <td>Transmission efficiency:</td> <td>11.75%</td> </tr> </table> <p>Circle One: <input checked="" type="checkbox"/> Pass / <input type="checkbox"/> Fail / <input type="checkbox"/> Exception</p> <p><i>Attach printouts of spectra, with peak intensities, peak width, and mass shift results, complete with the method file information, to the back of this protocol</i></p>	Transmission efficiency:	11.75%	09-julio-2024/ RSM
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<p>Comments: N/A</p>												
<p>Were there exceptions? Yes / <input checked="" type="checkbox"/> No <i>(If Yes, complete the exception reports(s) and attach them to the back of this protocol.)</i></p>												
<p>Reviewed By:</p>			<p>Date:</p>									



10.8. Operational Verification – Turbo V™ Ion Source Test

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date																
10.8.1	<p>Verify performance of the Turbo V™ ion source using both TurboSpray® and APCI probes.</p> <p>TurboSpray® (TIS) Set the temperature parameter to 500 °C</p> <p>APCI Set the temperature parameter to 400 °C</p>	<p>Verify: Turbo V™ ion source performance is as follows:</p> <table border="1" data-bbox="611 570 1171 776"> <thead> <tr> <th data-bbox="611 570 768 618">Probe</th> <th data-bbox="768 570 1171 618">Temperature reached in software</th> </tr> <tr> <th data-bbox="611 618 768 659"></th> <th data-bbox="768 618 1171 659">Specification</th> </tr> </thead> <tbody> <tr> <td data-bbox="611 659 768 719">TIS</td> <td data-bbox="768 659 1171 719">≥ 500°C</td> </tr> <tr> <td data-bbox="611 719 768 776">APCI</td> <td data-bbox="768 719 1171 776">≥ 400°C</td> </tr> </tbody> </table>	Probe	Temperature reached in software		Specification	TIS	≥ 500°C	APCI	≥ 400°C	<p>Verify: Turbo V™ ion source performance is as follows:</p> <table border="1" data-bbox="1207 570 1768 776"> <thead> <tr> <th data-bbox="1207 570 1365 618">Probe</th> <th data-bbox="1365 570 1768 618">Temperature reached in software</th> </tr> <tr> <th data-bbox="1207 618 1365 659"></th> <th data-bbox="1365 618 1768 659">Result</th> </tr> </thead> <tbody> <tr> <td data-bbox="1207 659 1365 719">TIS</td> <td data-bbox="1365 659 1768 719">500 C</td> </tr> <tr> <td data-bbox="1207 719 1365 776">APCI</td> <td data-bbox="1365 719 1768 776">500 C</td> </tr> </tbody> </table> <p style="text-align: center;">Circle One: Pass / Fail / Exception</p>	Probe	Temperature reached in software		Result	TIS	500 C	APCI	500 C	09-julio-2024/ RSM
Probe	Temperature reached in software																			
	Specification																			
TIS	≥ 500°C																			
APCI	≥ 400°C																			
Probe	Temperature reached in software																			
	Result																			
TIS	500 C																			
APCI	500 C																			

10.8. Operational Verification – Turbo V™ Ion Source Test

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
10.8.2	<p>Verify performance of the Turbo V™ ion source using both TurbolonSpray® and APCI probes.</p> <p>Test solution: Reserpine solution 0.0167 pmol/μL</p> <p>Flow Rate: 0.2 ml/min</p>	<p>Verify: Turbo V™ ion source performance is as follows:</p> <table border="1"> <thead> <tr> <th>Probe</th> <th>Signal Intensity of 609.3/195.1 transition, cps</th> </tr> </thead> <tbody> <tr> <td>TIS</td> <td>$\geq 2.0 \times 10^5$</td> </tr> <tr> <td>APCI‡</td> <td>$\geq 1.0 \times 10^5$</td> </tr> </tbody> </table> <p>‡Atmospheric pressure chemical ionization</p>	Probe	Signal Intensity of 609.3/195.1 transition, cps	TIS	$\geq 2.0 \times 10^5$	APCI‡	$\geq 1.0 \times 10^5$	<p>Verify: Turbo V™ ion source performance is as follows:</p> <table border="1"> <thead> <tr> <th>Probe</th> <th>Signal Intensity of 609.3/195.1 transition, cps</th> </tr> </thead> <tbody> <tr> <td>TIS</td> <td>298113</td> </tr> <tr> <td>APCI‡</td> <td>412433</td> </tr> </tbody> </table> <p>‡Atmospheric pressure chemical ionization</p> <p>Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p> <p><i>Attach the printouts of spectra, complete with the method file information, to the back of this protocol.</i></p>	Probe	Signal Intensity of 609.3/195.1 transition, cps	TIS	298113	APCI‡	412433	10-Julio-2024/ RSM
Probe	Signal Intensity of 609.3/195.1 transition, cps															
TIS	$\geq 2.0 \times 10^5$															
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Probe	Signal Intensity of 609.3/195.1 transition, cps															
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Comments: N/A																
Were there exceptions? Yes / <input checked="" type="checkbox"/> No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)																
Reviewed By:				Date:												





10.9. Operational Verification – Post-Test Pressure Verification

Note: Unless otherwise noted, all tests are performed using the Turbo V™ ion source with the TIS probe.

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date												
10.9.1	Verify the post-test vacuum pressure of the instrument.	<p>Post-test pressure in the vacuum chamber is as follows:</p> <table border="1"><thead><tr><th>CAD Gas Setting</th><th>Vacuum Chamber Pressure</th></tr></thead><tbody><tr><td>Zero (Off)</td><td>$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 0} \leq 1.1 \times 10^{-5} \text{ torr}$</td></tr><tr><td>12 (Full)</td><td>$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 12} - P_{\text{CAD } 0} \leq 2.8 \times 10^{-5} \text{ torr}$</td></tr></tbody></table>	CAD Gas Setting	Vacuum Chamber Pressure	Zero (Off)	$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 0} \leq 1.1 \times 10^{-5} \text{ torr}$	12 (Full)	$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 12} - P_{\text{CAD } 0} \leq 2.8 \times 10^{-5} \text{ torr}$	<p>Post-test pressure in the vacuum chamber is as follows:</p> <table border="1"><thead><tr><th>CAD Gas Setting</th><th>Vacuum Chamber Pressure</th></tr></thead><tbody><tr><td>Zero (Off)</td><td>0.4 x10-5</td></tr><tr><td>12 (Full)</td><td>2.0 x10-5</td></tr></tbody></table> <p>Circle One: <input checked="" type="checkbox"/> Pass / Fail / Exception</p>	CAD Gas Setting	Vacuum Chamber Pressure	Zero (Off)	0.4 x10-5	12 (Full)	2.0 x10-5	10-Julio-2024/ RSM
CAD Gas Setting	Vacuum Chamber Pressure															
Zero (Off)	$0.4 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 0} \leq 1.1 \times 10^{-5} \text{ torr}$															
12 (Full)	$1.8 \times 10^{-5} \text{ torr} \leq P_{\text{CAD } 12} - P_{\text{CAD } 0} \leq 2.8 \times 10^{-5} \text{ torr}$															
CAD Gas Setting	Vacuum Chamber Pressure															
Zero (Off)	0.4 x10-5															
12 (Full)	2.0 x10-5															

Comments: N/A

Were there exceptions? Yes / No (If Yes, complete the exception reports(s) and attach them to the back of this protocol.)

Reviewed By:

Date:

10.10. OQ Completion Verification

Test No.	Test Procedure	Acceptance Criteria	Actual Results	Initials / Date
10.10.1	Verify that all sections of the OQ Protocol have been completed.	All sections of the OQ Protocol have been completed.	Circle One: <input checked="" type="radio"/> Pass / Fail / Exception	10-Julio-2024/ RSM
10.10.2	Verify that any exceptions have been recorded.	Any exceptions have been recorded on an Exception Report and attached to the back of this protocol.	Circle One: <input checked="" type="radio"/> Pass / Fail / No Exceptions	10-Julio-2024/ RSM
Comments: N/A				
Were there exceptions? Yes / <input checked="" type="radio"/> No <i>(If Yes, complete the exception reports(s) and attach them to the back of this protocol.)</i>				
Reviewed By:			Date:	

11. OQ Report and Protocol Final Approval

Review and approve the OQ Protocol according to the procedures and quality system requirements of the organization that owns the instrument.

OQ Report and Protocol Final Approval	
Qualification Type	Circle one: Initial / Re-qualification
Summary of results	Circle one of the following
All qualification tests and measurements were successfully completed.	Pass
Some of the qualification tests or measurements required correction in order to successfully complete [‡] .	Pass after correction
Some of the qualification tests or measurements were not successfully completed.	Fail

[‡]An Exception Report must be attached showing the corrective action taken. The Exception Reports associated with this document are listed below.

11.1. Final Approval Signatures

	Printed Name	Signature	Initials	Title/Role	Date
Executed By	Salvador Jodra Chuan/ Roberto San Millan		SJC/RSM	FSE	11-Julio-2024/ RSM
Reviewed By	ADAN ALPIZAR		AAM	SCIENTIFIC DIRECTOR	

11.2. Exception Report Cross-Reference

List Exception Reports with cross-references, and attach all Exception Reports with supporting documentation to the back of this protocol.

Exception Report Number	OQ Protocol Page#	OQ Protocol Test Number	Problem Description	Resolution Date
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

11.3. Attachment Cross-Reference

List attachments with cross-references, and attach to the back of this protocol.

Attachment Number	OQ Protocol Test Number	Number of Attachment Pages	OQ Protocol Page # (X of XX)	Attachment Description
1	9.1.1	2	13 OF 56	TRAINING CERTIFICATES
2	9.4.2	6	17 OF 56	FLUKE CERTIFICATE
3	9.5.1	1	18 OF 56	PPG ANALYSIS CERTIFICATE
4	10.4.1	2	31 OF 56	SERVICE CONTRACT
5	10.7.1	32	39 OF 56	Q1 POS
6	10.7.2	32	42 OF 56	Q3 POS
7	10.7.3	32	45 OF 56	Q1 NEG
8	10.7.4	32	48 OF 56	Q3 NEG
9	10.7.5	14	49 of 56	MSMS PERFORMANCE
10	10.8.2	16	51 OF 56	ION SOURCE TEST



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