

OQ

for ET 210 *Inert* eluent tray

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C H A P T E R 1

Introduction

This document describes the Operation Qualification procedure as advised by the manufacturer. It is a result from our interpretation of many regulations and laboratory practices. In addition, feedback from users and representatives helped us to finalize this procedure.

As regulations and customer requirements may change, manufacturer reserves the right to introduces changes without prior notice. For details on functionality, operation and theory we refer to the instrument user manuals.

In this document, all qualification checks have to be approved, or should be marked "n.a." if not applicable. Any deviation observed must be documented in the 'non-conformance' record. All relevant documents regarding this qualification must be filed together in one location.

C H A P T E R 2

OQ procedure

Introduction

The Operation Qualification (OQ) consists of a visual and functional check of the ET 210^{inert} eluent tray. The visual check covers the condition of the quick connectors and used eluent bottles, while the functional check focusses on the functionality of the flow regulation, manometer readout and leak tightness.

Required parts, tools and software

Required parts and tools

- ET 210^{inert} eluent tray
- Regulated Nitrogen or Helium 5.0 supply with open/close valve
- Beaker with DI water
- Timer

Test 1: Visual check of quick connectors

The ET 210^{inert} eluent tray consists of multiple quick connectors to connect both eluent and gas tubing. The condition of these quick connectors is crucial for leak-free operation.

Procedure

1. Disconnect all quick-connectors if any connections were made already.
2. Inspect the female-quick connectors in the ET 210^{inert} eluent tray: no damage should be observed on the in- and outside of the connector.
3. Inspect the 4 gas lines (red or blue) used to supply the eluent bottles with inert gas: the male quick-connector must be undamaged and the black O-ring must not be dried out.
4. Connect all 4 gas lines to the ET 210^{inert} eluent tray. Check that the connector snaps in place properly and could be removed when pressing the release button of the inert gas outlet connector.
5. Repeat this procedure for the connections on the eluent lines connecting the eluent bottles to the LC pump.
6. Write the results (passed or failed) in the OQ results summary – section Visual checks: Quick connectors.

Test 2: Visual check of eluent bottles

Although indirectly being part of the ET 210^{inert} eluent tray, the condition of the eluent bottles is key for successful operation. This test verifies whether the eluent bottles show any visual shortcomings which could potentially lead to leakage or issues maintaining a proper headspace.

Procedure

1. Disconnect all eluent bottles if any connections were made already.
2. Unscrew the caps and inspect the bottles for visual damage. Ensure that the top of the bottle is smooth in case of a PPCO bottle.
3. Inspect the caps for missing, damaged or loose connectors. Make sure that the eluent line is unbent and reaches the bottom of the bottle.
4. Screw the cap back onto the bottle and ensure that this screws on in a smooth motion.
5. Write the results (passed or failed) in the OQ results summary – section Visual checks: Eluent bottles.

Test 3: Functional check of flow regulator valve

The flow regulator valve is used to switch between sparging and blanketing of the eluent. In order to control this, the functionality of this valve is checked.

Procedure

1. Disconnect any previous connections made to the gas outlets of the ET 210^{inert} eluent tray.
2. Connect one of the inert gas supply lines to inert gas outlet A. Place the end of the tubing in a beaker filled with DI water.
3. Turn the blue flow regulator valve counter-clockwise and confirm that the gas flow increases.
4. Turn the blue flow regulator valve clockwise and confirm that the gas flow decreases.
5. Repeat this procedure for gas outlets B, C and D.
6. Switch the flow back to blanketing position. If required, adjust the position of the locking ring.
7. Write the result (passed or failed) in the OQ results summary – section Functional checks: flow regulator valve.

Test 4: Functional check of manometer

The manometer represents the functionality of the internal pressure regulator, making it a key component of the eluent tray. Functionality of the manometer is confirmed by checking its reading with and without flow.

Procedure

1. Disconnect any previous connections made to the gas outlets of the ET 210^{inert} eluent tray.
2. Close the laboratory gas supply to stop the flow of gas to the tray.
3. Connect an open inert gas supply line to any of the inert gas outlets to release any remaining gas from the eluent tray.
4. Confirm that the pressure readout decreases and that the manometer shows 0 bar when all gas is released.
5. Remove the inert gas supply line and open the laboratory gas supply.
6. Allow the pressure to stabilize and read the pressure on the manometer. This should be between 0.2 and 0.6 bar.
7. Write the results (pressure readouts) in the OQ results summary – section Functional checks: manometer.

Test 5: Functional check – gas tightness

As a final test, the leak tightness of the tray is tested. This ensures the low gas consumption of the ET 210^{inert} eluent tray. The test result is based on the pressure drop during a 30-minute interval.

$$P_{\Delta} = P_{start} - P_{end}$$

Formula 1: Gas tightness

Procedure

1. Disconnect any previous connections made to the gas outlets of the ET 210^{inert} eluent tray.
2. Close the laboratory gas supply to stop the flow of gas to the tray.
3. Write down the pressure readout on the manometer (P_{start}).
4. Start a timer for 30 minutes and check the pressure readout at the end (P_{end}).
5. Calculate the pressure deviation during this 30-minute interval using formula 1 above. This may not exceed 0.1 bar.
6. Write the results (pressure readouts) in the OQ results summary – section Functional checks: gas tightness.

C H A P T E R 3

OQ results summary**Test results**

	Specified	Measured	Result^{*1}
<u>Visual checks</u>			
Quick connectors			
Channel A	Inspect		
Channel B	Inspect		
Channel C	Inspect		
Channel D	Inspect		
Eluent bottles			
Bottle A	Inspect		
Bottle B	Inspect		
Bottle C	Inspect		
Bottle D	Inspect		
<u>Functional checks</u>			
Flow regulator valve			
Flow regulator valve	Functional		
Manometer			
Reading without flow	0 bar	 bar	
Reading with flow	0.2 – 0.6 bar	 bar	
Gas tightness			
Pressure drop in 30 minutes	< 0.1 bar	Start: bar End: bar Δ: bar	

*1 Fill in 'passed' or 'failed'

Final result (passed / failed) _____

Verified by (customer):

Deviations (Y/N):

Comments:

C H A P T E R 4

OQ certification

The undersigned reviewer/customer is authorized to sign and accepts that the engineer is trained and qualified to perform the Qualification procedures on Antec devices.

The undersigned engineer certifies that he/she is trained and qualified to perform the Qualification procedures on Antec devices.

All tests and procedures as described in this document have been completed, and all results are within specifications or clearly indicated if not.

The installation and operation testing has been carried out in accordance to the OQ procedures and to the satisfaction of both parties.

Engineer

Name
Initials
Company

.....
Date Signature

Reviewer/customer

Name
Initials
Job title
Company & Dept.

.....
Date Signature

Instrument

ET 210

p/n:

s/n:

Accessories

Bottle A Type:

Bottle B Type:

Bottle C Type:

Bottle D Type:

Fill in 'PPCO 2L', 'PPCO 4L', 'Glass 1L' or 'n.a.'

Test conditions

Gas regulator Brand: Model:

Inert gas Type: N₂ / He Purity:

Inlet gas pressure bar

Other relevant information

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Verified by (customer):

Deviations (Y/N):

Comments:

Comments

Verified by (customer):

Deviations (Y/N):

Comments:

C H A P T E R 5

Non-conformance record

Any case of non-conformance found during the qualification procedure should be documented and signed for acceptance or corrective action taken.

Table I

Ref.	Non-conformance and action taken	Signature customer	Sign. executing technician
1			
2			
3			
4			
5			
6			

Verified by (customer):

Deviations (Y/N):

Comments: