

Molecular Imaging Core
Department of Diagnostic Imaging

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<h1>EQUIPMENT QUALIFICATION</h1>	
Asset Code	
Asset Name	

	Name	Position	Date
Prepared By			
Approved By			
Executed By			
QUALIFICATION RESULT		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Comments			

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1. SCOPE

The following document describes and collects the results the Installation Qualification (IQ), Operational Qualification (OQ) of the Testbed for vacuum pumps in compliance with FDA. 823 Positron Emission Tomography Drugs for Compounding , Investigational , and Research Uses (2016) and FDA 21 CFR Part 211 - cGMP for finished pharmaceuticals.

2. PURPOSE

- Collect instrument identification data
- Verify that the instrument has been installed according to the manufacturer's specifications
- Verify the availability of user manuals and other technical documentation
- Verify that the instrument components operate as described in the user manual.

3. REFERENCES

FDA. 823 Positron Emission Tomography Drugs for Compounding , Investigational , and Research Uses (2016).

FDA 21 CFR Part 211 - cGMP for finished pharmaceuticals.

4. INSTALLATION QUALIFICATION TESTS

4.1. Identification

Parameter	Result
Asset number	
Name	
Serial number	

4.2. Location

Parameter	Result
Physical location	

4.3. Instrument Documentation

Parameter	Acceptance criteria	Result	
User manual available	Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Parts list available	Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Copy of firmware available	Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Maintenance plan available	Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pressure sensor calibration certificate available	Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pressure sensor calibration certificate expiration			
Control software version			
Logger software version			

4.4.Fluidic Connections

Parameter	Acceptance Criteria	Result	
Inert gas	Connected to suitable gas, such as nitrogen, argon, or helium	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Liquid waste	Connected to collection container	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Gas waste	Connected to collection container	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

4.5.Electrical Connections

Parameter	Acceptance Criteria	Result	
Electrical power supply	Connected to wall receptacle	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Internal electrical connections	Connected as described in manual	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5. OPERATION QUALIFICATION TESTS

5.1. Testbed

5.1.1. Start-up

Prepare the Testbed for use as outlined in section 5.1. of the Testbed User Manual.

Parameter	Acceptance Criteria	Result	
Connect the inert gas supply line to the Testbed's GAS IN port	The green light in the power entry module turns on	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Plug it in to the electrical outlet.	LCD shows a welcome message	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Toggle the power switch in the power entry module to the ON position	All valves remain closed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.2. System suitability test

Follow the steps in section 5.2 of the Testbed User Manual to prepare the unit for a system suitability test.

Parameter	Acceptance Criteria	Result	
Press PRESSURIZE	The green ring on the PRESSURIZE button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is PRESSURIZE	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S15 opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S16 opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Record pressure reading	Stable above 205 kPa. Pressure: _____ kPa	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Press HOLD Record the pressure drop after 3 minutes	Pressure drop is below 3 kPa. Pressure drop: _____ kPa	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.3. Exhaust selection

1. Connect the lines labeled TO INTAKE and FROM EXHAUST together using a female push-in coupling fitting.
2. Verify that the exhaust selection toggle switch is in the GAS WASTE position.

Parameter	Acceptance Criteria	Result	
Press VACUUM	Valve S14-G opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S14-L remains closed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Gas comes out of the GAS WASTE port on the rear of the Testbed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Push the paddle of the exhaust selection toggle switch from the GAS WASTE to the LIQUID WASTE	The paddle on the toggle switch illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S14-G closes	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S14-L opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Gas comes out of the LIQUID WASTE port on the rear of the Testbed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.4. Mode: PRESSURIZE

Install a pump as described in section 5.3. of the Testbed User Manual.

Parameter	Acceptance Criteria	Result	
Press PRESSURIZE	The green ring on the PRESSURIZE button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is PRESSURIZE	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S15 opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S16 opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Pump remains off	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.5.Mode: CYCLE

Install a pump as described in section 5.3. of the Testbed User Manual.

Parameter	Acceptance Criteria	Result	
Press CYCLE	The green ring on the CYCLE button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is CYCLE	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The green ring on the CYCLE button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is CYCLE	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The pump turns on	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows the current absolute pressure in the pump's supply line	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S15 remains open	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S14-G opens sporadically to maintain 75 kPa in the pump's supply line	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Toggle PUSH for 1 to 2 seconds	The paddle on the toggle switch illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	S16 Opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Pressure increases	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Release PUSH	The paddle returns to its original position	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S16 closes	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.6.Mode: VACUUM

Install a pump as described in section 5.3. of the Testbed User Manual.

Parameter	Acceptance Criteria	Result	
Press VACUUM	The green ring on the VACUUM button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is VACUUM	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Valve S14-G opens	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The pump turns on	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.7.Mode: HOLD

Install a pump as described in section 5.3. of the Testbed User Manual.

Parameter	Acceptance Criteria	Result	
Press HOLD	The green ring on the HOLD button illuminates	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The LCD shows that the current mode is HOLD	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	All valves remain closed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The pump remains off	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.1.8.Mode: VENT

Parameter	Acceptance Criteria	Result	
Press VENT	The LCD shows that the Testbed is being vented and show a countdown.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	All valves remain closed	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The pump remains off	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

5.2. Logger application

1. Prepare the Testbed for use as outlined in section 5.1. of the Testbed User Manual.
2. Install a pump as described in section 5.3. of the Testbed User Manual.
3. Open the Testbed Logger application.
4. Connect the Testbed using a USB-A to USB-B cable.

Parameter	Acceptance Criteria	Result	
Press CONNECT	Connection is successful	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Application turns to the Main Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Type "AAA" in the "Pump Asset Tag" data field.	Text remains in the data field.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Type "111" in the "Pump Run Hours" data field.	Text remains in the data field.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Verify that the "Pump being rebuilt?" slider is in the "Before" position.	N/A	N/A	N/A
Purge the pump as described in section 5.4 of the Testbed User Manual	Pressure reading appears on the Chart Panel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Pressure values match the reading on the Testbed's LCD	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Execute a vacuum test as described in section 5.5 of the Testbed User Manual	Pressure reading appears on the Chart Panel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Test carries on as defined in the Settings Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	At the end of the test, the vacuum test status checkbox changes from "Pending" to "Complete"	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Execute a pressure test as described in section 5.6 of the Testbed User Manual	Pressure reading appears on the Chart Panel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Test carries on as defined in the Settings Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	At the end of the test, the vacuum test status checkbox changes from "Pending" to "Complete"	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Switch to the Results Tab	The test code is "AAA-BEFORE-YYYYMMDD-HHMM"	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

	The results tables are consistent with the test values	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The results plots are consistent with the test values	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Pump being rebuilt?” slider is in the “Before” position	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Pump asset tag” is “AAA”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “operator” data field matches the current Windows user name.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Run hours” data field shows “111”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Press Save	The report is saved in the designated storage location.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Browse to the storage location using Windows file explorer and open the test report	The report is an accurate replica of the contents of the Results Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Return to the Main Tab	N/A	N/A	N/A
Click on the “Pump being rebuilt?” slider	The slider changes to the “After” position	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Execute a vacuum test as described in section 5.5 of the Testbed User Manual	Pressure reading appears on the Chart Panel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Test carries on as defined in the Settings Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	At the end of the test, the vacuum test status checkbox changes from “Pending” to “Complete”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Execute a pressure test as describe in section 5.6 of the Testbed User Manual The vacuum test status checkbox changes from “Pending” to “Complete”	Pressure reading appears on the Chart Panel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	Test carries on as defined in the Settings Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	At the end of the test, the vacuum test status checkbox changes from “Pending” to “Complete”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Switch to the Results Tab	The test code is “AAA-AFTER-YYMMMDH-HHMM”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

	The results tables are consistent with the test values	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The results plots are consistent with the test values	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Pump being rebuilt?” slider is in the “After” position	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Pump asset tag” is “AAA”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “operator” data field matches the current Windows user name.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
	The “Run hours” data field shows “111”	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Press Save	The report is saved in the designated storage location.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Browse to the storage location using Windows file explorer and open the test report	The report is an accurate replica of the contents of the Results Tab	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail