


Installation and Operational qualification

Masterflex Peristaltic Pump

77410-10.




| | |
|-------------------------|---|
| PUMP DRIVE CATALOGUE NO | PERISTALTIC PUMP MODEL 77410-10 |
| DOCUMENT NO | MF/IQOQ/RV/2206/2023 |
| DATE | 22 JUN 2023 |
| REVISION NO | 1.2.1 |
| CUSTOMER NAME | M/S INDIAN IMMUNOLOGICALS LIMITED |
| LOCATION | RAKSHAPURAM, GACHIBOWLI , HYDERABD-500032 |

| | | |
|---------------|---|---|
| IOQ | PERISTALTIC PUMP MODEL 77410-10 |  |
| DOCUMENT NO | MF/IQOQ/RV/2206/2023 | |
| DATE | 22 JUN 2023 | |
| REVISION NO | 1.2.1 | |
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| LOCATION | RAKSHAPURAM, GACHIBOWLI , HYDERABD-500032 | |


POINTS TO BE NOTED WHILE FILLING THIS DOCUMENT

- The tests/checks shall be performed as per the defined IOQ procedures or test sections. The observations will be recorded within the defined Observation tables with a blue ball point indelible ink.
- Test sections which do not apply to the system for testing/qualification shall be marked as “Not applicable” (NA) by striking through with a blue ball point indelible ink. All empty spaces should also be marked as NA.
- Correction of data entry error will be done by striking through the incorrect data with a single line. The person making the data change will need to sign-off and enter the date when the change was made.
- Date format of “ DD.mm.YY ” to be adhered to. All entries should be made in current date, backdating is strictly prohibited.
- Each individual Test should have a provision for “Checked by” and “Verified by” column. Vendor/Consultant will perform the test and sign under “Checked by” column after executing the test and filling the test observations.
- The test summary report should be filled as “PASS” against each criteria where the tests meet the pre-defined acceptance criteria after successful completion and “FAIL” for the tests which do not meet the acceptance criteria.
- Deviations need to be recorded for the tests which “FAIL” to meet the acceptance criteria.
- Tests which “FAIL” to meet the acceptance criteria need to be re-tested.
- The IOQ documentation and procedure has been designed and accepted by both the customer (M/S Indian Immunologicals Ltd) and supplier (Avantor Performance material India Pvt Ltd.).
- This document is a property of Masterflex, Part of Avantor. Should not be copied/Altered any part or full without written authorization from the company.

| | | |
|----------------------|---|--|
| IOQ | PERISTALTIC PUMP MODEL 77410-10 |  MASTERFLEX [®] part of avantor |
| DOCUMENT NO | MF/IOQ/RV/2206/2023 | |
| DATE | 22 JUN 2023 | |
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| LOCATION | RAKSHAPURAM, GACHIBOWLI , HYDERABD-500032 | |

LIST OF ABBREVIATIONS

| | | | |
|---------------|----------------------------|----------------|---------------------------|
| IQ | Installation Qualification | OQ | Operational Qualification |
| RPM | Revolution Per Minute | mL | Milli liters |
| LPH | Liters Per Hour | V | Voltage |
| Hz | Hertz | °C | Degree Celsius |
| Sr. #. | Serial Number | Model # | Model Number |
| mA | Milli Ampere | mL/min | Milliliter per minute |
| Mg | Milligram | % , / | Percentage, Division |
| Hp | Horsepower | PO | Purchase Order |





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1.0 PRE- APPROVAL


M/s. Avantor Performance Materials India Pvt Ltd

| Prepared By | | Signature | Date |
|-------------|----------|---|----------|
| Name | Rajesh.V |  | 23.06.23 |

M/s. Indian Immunologicals Limited

| Reviewed by User | | Signature | Date |
|------------------|-------------------|---|----------|
| Name | M. Ravileja |  | 23.06.23 |
| Name | BVVS Sailesh |  | 23.06.23 |
| Reviewed by | | Signature | Date |
| Name | N. Srinivasa Rao. |  | 23.06.23 |
| Name | V. Sai Chand |  | 23.06.23 |

| Approved By QA | | Signature | Date |
|----------------|------------|--|----------|
| Name | A-K Choban |  | 23.06.23 |

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2.0 OBJECTIVE


The objective of this document is to provide a written guideline & protocol to carry out the Installation Qualification (IQ) and Operational Qualification (OQ) of Masterflex Peristaltic Pump model 77420-30

3.0 SCOPE

This protocol is applicable to Masterflex Peristaltic pump supplied by M/s Avantor performance Material India Pvt Limited., installed at B-6 block, Down Stream-2
at m/s Indian Immunologicals Ltd, Gachibowli,

This protocol provides an outline for the Installation Qualification (IQ) and Operational Qualification (OQ) of the equipment for static attributes and verifies that:

- 3.1 The system is installed according to the design specifications and manufacturers recommendations.
- 3.2 Each installed subcomponent complies with the engineering design and equipment data sheets/specifications given by the manufacturer.
- 3.3 No unauthorized or unrecorded modifications have taken place to the unit.
- 3.4 Standard Operating Procedures including operation and preventive maintenance have been identified and listed.
- 3.5 All critical instrumentation has been identified for calibration of the equipment.
- 3.6 All supporting utilities are properly connected.
- 3.7 All installation-testing reports are available and attached.

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4.0 RESPONSIBILITY


The qualification group comprises of representatives from each of the following departments and shall be responsible for the overall compliance of this protocol:

| M/S. Avantor Performance Material India Limited. | Responsibility |
|--|--|
| Vendor | Responsible for preparation of this protocol, installation and recording the installation data as per the prescribed procedures for this protocol. |

| M/S Indian Immunologficals Limited | Responsibility |
|------------------------------------|--|
| User's Department | Responsible for checking and reviewing the data recorded in the protocol and review of summary report. |
| Engineering Department | Responsible for checking and reviewing the data recorded in the protocol and review of summary report. |
| Quality Assurance | Responsible for the final review and approval of this protocol. |

5.0 EQUIPMENT IDENTIFICATION

| | |
|-----------------|---|
| Product Name | Peristaltic Pump |
| Equipment Model | 77410-10+77602-10 |
| Equipment Sr | 0423042652, 0922003791 |
| Supplier Name | Avantor Performance Materials India Private Limited |

| | | |
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6.0 EQUIPMENT LOCATION


| | |
|------------------------|--------------------------|
| Department | B-6 Block, Down Stream-2 |
| Room Name | Down Stream-2 |
| Other details (if any) | NA |

7.0 SPECIFICATION*

| | |
|------------------------------------|---|
| Max flow rate (mL/min) | 7000** |
| Min flow rate (mL/min) | 500** |
| Control type | Digital Variable Speed |
| Power (Amps) | 0.8 at 230 VAC |
| Motor (watts) | 280 |
| Reversible motor | Yes |
| RPM | 33-650 |
| IP rating (Drive) | IP55 |
| Digital dispensing | Yes |
| Dimensions (Drive) | 14"L x 10"W |
| Speed control | ±0.25% |
| No. of Pump heads accepted | 2, only easy load. |
| Type of Pump heads accepted | Standard, Easy-Load, Easy-Load II, Quick Load, High Performance, Cartridge, Multichannel, PTFE Tubing, PTFE Diaphragm |
| Brand | Masterflex |
| Model | 77410-10 |
| Humidity | 40 to 95% |
| Temperature | 5-50 degree C |

** Maximum and Minimum flowrate is approximated on theoretical values considering the tubing formulation, tubing size and pump head for water only. Practically this may vary.



* For information only. This will not be verified during the qualification.


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8.0 INSTALLATION QUALIFICATION PROCEDURE

8.1 General Installation Check Points:



| Sl. No. | Statement | Acceptance Yes / No |
|---------|--|---------------------|
| 1 | The major components are securely anchored and protected from shock. | Yes |
| 2 | There is no observable physical damage. | Yes |
| 3 | Verify that the required electric connections are tight, weather proofed and grounded. | Yes |
| 4 | The unit(s) are installed as per manufacturer's recommendations. | Yes |
| 5 | All access ports are examined and cleared of any debris. | Yes |
| 6 | Verify that sufficient room for servicing and cleaning is provided. | Yes |
| 7 | The equipment identification nameplate along with equipment number is visible. | Yes |
| 8 | The machine manual is available. | Yes |
| 9 | The temperature and humidity are within the specified limit (Refer specification for details). | Yes |
| 10 | There is no excess dust. | Yes |

| Particulars | Name | Signature | Date |
|---------------------|-------------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | M. Ravileja |  | 23.06.23 |

| | | |
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8.2 Check for physical damages during transportation / installation:

| Sl. No. | Product Description | Specified | Observations Pass/Fail | Acceptance Yes/No |
|---------|------------------------|--|------------------------|-------------------|
| 1 | Peristaltic pump drive | There should not be any damage to the instrument | Pass | Yes |
| 2 | Pump Head | There should not be any damage to the Pump Head | Pass | Yes |
| 3 | Tubing | There should not be any damage to the tubing supplied. | Pass | Yes |

| Particulars | Name | Signature | Date |
|---------------------|-------------|--|----------|
| Checked By (Vendor) | Rajesh V |  | 23.06.23 |
| Verified By (User) | m. Ravilepa |  | 23.06.23 |



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8.3 List of Test equipment(s) used for the calibration:



| | |
|----------------------------|----------------------|
| Equipment Name | weighing Balance |
| Model #. | CP 5202 (B6/web/164) |
| Serial #. | 16702480 |
| Calibration Date | 12.06.23 |
| Calibration Certificate #. | SCS/06-23/1331-02 |
| Calibration Validity | 19.06.24 |


| Particulars | Name | Signature | Date |
|------------------------|-------------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | M. Raviteja |  | 23.06.23 |

| | | |
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8.4 Safety checks and precautions:

1. Connect the instrument to a 230V, properly earthed single phase voltage outlet only.
2. Never load the tubing when pump is working. Before loading the tube ensure that the pump is switched OFF.
3. Use only Masterflex recommended tubing with the pump.
4. Inspect the screws fitting the head to drive once in a month.
5. If any fluid leakage is observed due to the puncture in the tube, switch off the pump immediately. Clean the rollers immediately with mild detergent and water or use an appropriate solvent.



| Particulars | Name | Signature | Date |
|------------------------|-----------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | m.Ravikap |  | 23.06.23 |


| | | |
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8.5 Utilities:

| Description | Requirement | Actual |
|----------------------|--|--------------|
| Power supply Voltage | 230V +/- 10% * | 232 V |
| Stabilizer | Required stabilized voltage (As above) | Satisfactory |
| Earthing | Good earthing | Satisfactory |

- For information and verification only. No need to establish with a calibrated device as this is not a process parameter from instrument

| Particulars | Name | Signature | Date |
|------------------------|-------------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | m. Ravileja |  | 23.06.23 |

| | | |
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9.0 OPERATIONAL QUALIFICATION PROCEDURE

9.1 Tests for Key Functionality and Safety Features:


Instructions:


- Check the equipment / system in the entire operating range to ensure that the unit is working within the desired design specification, (as per manual).
- Verify the pre-start up checks.
- Verify the functions of each component against its specified functions.
- Verify the safety features of the equipment / system are working as per the intended specifications.
- Record observations.

| Sr.# | Test Particulars | Specified Function | Observations Pass/Fail (Circle appropriate) |
|------|--|--|---|
| 1 | All keys on the keypad | All keys should respond for its pressing | Pass/Fail |
| 2 | Percentage RPM setting in a scale of 5-100 | Turn the speed control potentiometer and verify the minimum setting of "5" and Maximum setting of "100" | Pass/Fail |
| 3 | Start/Stop Key | Operate this key and ensure the pump is starting and stopping with the operation of this key. | Pass/Fail |
| 4 | Forward and Reverse flow | Please set the flow in clock wise direction and start the pump. Also set the counter clock wise direction and verify the same. | Pass/Fail |
| 5 | Pump head check | Check for the head and load the tubing. Check whether the tube is loading properly or not | Pass/Fail |
| 6 | Operational check | Fix a suitable tubing in the pump head. Take trails with water and check whether proper pumping is taking place or not. | Pass/Fail |

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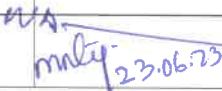
| Sr.# | Test Particulars | Specified Function | Observations Pass/Fail (Circle appropriate) |
|------|------------------|--|---|
| 1 | Input voltage | Stabilized input voltage of 230V+/- 10% is required * | Pass/Fail |
| 2 | Shock/earthing | Check for proper earthing and ensure that instrument does not give shock to the operator | Pass/Fail |
| 3 | Water spillage | Ensure that no water should be spilled on the instrument from the neighboring water pipes/Connections. | Pass/Fail |

| | Name | Signature | Date |
|---------------------|------------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | m.Raviteja |  | 23.06.23 |

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9.2 Training:


Title : operation and maintenance of masterflex
 Date : Peristaltic Pump .
 23-06-23
 Name of the Trainer(s) : Rajesh.V

| Sr. # | Name of the Trainee | Employee Number | Department | Signature |
|-------|---|-----------------|------------|---|
| 1 | BVVS Sailesh | 6301 | Production |  |
| 2 | B. Udaykumar | 7333 | Production |  |
| 3 | K. Panduranga Reddy | 007882 | Production |  |
| 4 | M. Raviteja | 004573 | Production |  |
| 5 |  | | | |
| 6 | | | | |

Signature of Trainer(s) : 

Date : 23.06.23

| | Name | Signature | Date |
|---------------------|-------------|--|----------|
| Checked By (Vendor) | Rajesh.V |  | 23.06.23 |
| Verified By (User) | M. Raviteja |  | 23.06.23 |

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9.3 Flow check

Check the Flow rate of the pump as described. Use a calibrated analytical balance (Customer should provide) with desirable accuracy of 1g/10g

| | |
|---------------------------------|---------------------------------|
| calibration date of used device | 12.06.23 |
| Model and Serial No | CPS202 (B6 /WEB /164), 16702480 |
| Calibration Expiry date | 19.06.24 |

Procedure:


Set the RPM to 10%, 50% and 100%. Operate the pump in these 3 flow rates. Ensure that the tube is filled completely. Switch the pump ON. Operate the pump as described in the operating manual.

| Sr. # | Flow rate selected in % RPM | Measured volume(ml) | Remarks |
|-------|--|---------------------|----------|
| 1 | 10 | 872.83 | Verified |
| 2 | 50 | 4394.97 | Verified |
| 3 | 100 | 8394.02 | Verified |
| 4 | <hr/> NA 23.06.23 | | |


Masterflex Tubing Catalogue No : 96410-73



Inner Diameter9.6..... mm; Outer diameter.....16.....mm


*Accuracy may vary with tubing dimensions and formulations. This procedure is performed with only one size of tubing.

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9.4 Deviation and corrective action (if any):

| Particulars | Deviations and corrective actions (if any) | Signature |
|-----------------------|--|---|
| No deviation observed | NA |  |
| | NA | |
| | | |



| | Name | Signature | Date |
|----------------------|-------------|--|----------|
| Executed By (Vendor) | Rajesh.V |  | 23.06.23 |
| Witnessed By (User) | M. Raviteja |  | 23.06.23 |

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10.0 ACCEPTANCE CRITERIA


Installation Qualification and Operational qualification shall be considered acceptable only when all the conditions Specified under Sections 8.0 and 9.0 have been met. Any deviation from the acceptance criteria of the specific checkpoint shall be reported and decision should be taken for the rejection, replacement, or rectification of the equipment/component.

11.0 SUMMARY

| Checks | Observations | Remarks |
|--|--|---|
| Whether acceptance criteria of the protocol and Specific check points are met. |  YES/NO |  |


12.0 CONCLUSION



Peristaltic pump 77410-10 IS / IS NOT qualifying the installation /Operational qualification test as per the guideline described in this IQ protocol.





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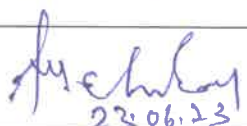
13.0 POST APPROVAL


M/s. Avantor Performance Materials India Limited

| Performed By | Signature | Date |
|----------------------|---|-----------------|
| Name <i>Rajesh V</i> |  | <i>23.06.23</i> |

M/s. India Immunologics Limited

| Reviewed by User | Signature | Date |
|-------------------------------|--|-----------------|
| Name <i>M. Ravilep'a</i> |  | <i>23.06.23</i> |
| Name <i>BVVS Sailesh</i> |  | <i>23.06.23</i> |
| Reviewed by | Signature | Date |
| Name <i>N. Srinivasa Rao.</i> |  | <i>23.06.23</i> |
| Name <i>V. Sai Chand</i> |  | <i>23.06.23</i> |

| Approved By QA | Signature | Date |
|-------------------------|---|-----------------|
| Name _____ |  | _____ |
| Name <i>A.C. Chokan</i> |  <i>23.06.23</i> | <i>23.06.23</i> |

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14.0 ANNEXURES

| Sr. No | Description | Document number (if any) | No.of pages |
|---------------------------|--|--|----------------|
| 01 | Installation Report | Nil | 01 |
| 02 | weighing Balance calibration certificate | SGS/06-23/1331-02 SES/06-22/1408/02 | 02 |
| <i>NA. mulep 23.06.23</i> | | | |
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