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# version control history

|  |  |  |  |
| --- | --- | --- | --- |
| Date | *Issue No.* | *CCR* | *Change description / reason / supersedes* |
| 25-May-10 | 01 | Nil | New Document |

# what

This document details the procedure for the Operation and Calibration of Conductivity Meter.

# why

It is the policy of Xyz Pharmaceuticals Limited that a written procedure shall be followed the Operation and Calibration of conductivity meter and its use monitored in order to ensure smooth operation and its use monitored to obtain consistent and reproducible results and to minimise down time and to meet regulatory requirements.

# when

This procedure is to be applied at the time of Operation and Calibration of Conductivity meter.

# RESPONSIBILITY AND accountability

Persons along with their responsibilities and accountability are given below:

|  |  |  |
| --- | --- | --- |
| Sr. No | Designation | Responsibility |
| 01 | Executive – Corporate Quality Assurance | To prepare the SOP. To maintain the records as per SOP. |
| 02 | Trainee Analyst/ Jr. Analyst/ Analyst/ Sr. Analyst | To follow the SOP accordingly |
| 03 | Section - In Charge | To ensure implementation of SOP. |
| 04 | Manager - Technical | To ensure implementation of SOP. |
| 05 | Vice President - Technical | To ensure implementation of SOP. |
| 06 | Manager – Quality Assurance | To ensure implementation of SOP. |
| 07 | Assistant - General Manager | To ensure implementation of SOP. |

## PROCEDURE

**5.1 PRELIMINARY CHECK**

5.1.1 Check if the instrument is clean and free from dust, if not; clean with a soft cloth duster.

5.1.2 Ensure that the temperature sensor is always dipped in purified water.

5.1.3 Ensure that the temperature is about ambient and relative humidity is about 45%.

**5.2** **STORAGE & CARE OF ELECTRODE:**

5.2.1 Store the cell in purified water.

5.2.2 Clean the electrode thoroughly by stirring it in a mild detergent or isopropyl alcohol. Wipe the probe with a soft tissue paper, rinse with tap water and then with purified water.

5.2.3 Never scratch the platinum coated portion with a hard substance.

5.2.4 Do not immerse the probe in any oily solutions.

#### **5.3 PRECAUTIONS**

5.3.1 Keep the conductivity probe clean and dry. Rinse the probe 2 - 3 times to remove the carry over and gently swirl it while taking the readings.

5.3.2 Electrode and (Resistance Temperature Detectors) RTD sensor should always be used in vertical position.

5.3.3 Ensure that the solution is above the cell tip and below the vent hole and there is no air bubble trapped inside the chamber before actual measurement. To reduce the air bubbles always immerse the probe in the solution slowly at an angle and then make it vertical.

5.3.4 Electrodes should be rinsed between sample measurements with distilled water or purified water. Never rub the electrode to remove excess water, just blot the tip end of the electrode with a clean tissue paper to remove residual drops.

5.3.5 Allow sufficient time for the probe to stabilise in the sample response as given under

5.3.6 For the greatest accuracy, ensure that no particulate matter is suspended in the test solution. If necessary, filter the solution before the determination of conductivity.

**5.4 OPERATION**

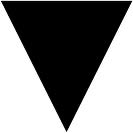
5.4.1 Connect the plug to the main power supply.

5.4.2 Switch on the main switch. The instrument shows following display on the seen:

|  |
| --- |
| **ELICO LIMIT ED**  **INDIA** |

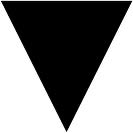
5.4.3 Press “MODE” key on the front panel EC-TDS C°display appears.

5.4.4 Use up ()and down () key to select EC-TDS or C° and press “ENT” key.



5.4.5 Use ESC key to return to the previous menu.

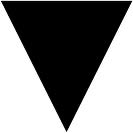
5.4.6 Use up () and down ()key to select the required option say EC-TDS and then press “ENT” key.



* + 1. Instrument display: SELECT MODE

EC TDS

5.4.8 Again Use up () and down () key to select EC or TDS say EC and then press “ENT” key.



5.4.9 Enter cell constant 1.00 and then press “ENT” key.

5.4.10 Instrument display EC @ 25 Cº. Note the reading.

5.4.11 Switch off the instrument when not in use.

5.4.12 Maintain the Log book of Conductivity Meter on XYZ/CQA/SOP-070/FR-01 Log book for Conductivity meter Appendix I.

**6.0 CALIBRATION PROCEDURE**

6.0.1 Calibration Frequency: Quarterly

### 6.0.2 Ensure that the Electrode is connected to instrument and is properly cleaned and stored.

6.0.3 Ensure the temperature sensor is connected to instrument.

6.0.4 Rinse the Conductivity Electrode with purified water 2 - 3 times; remove the excess water by using a tissue paper.

6.0.5 Take the standard solution of known conductivity in a clean beaker. Dip the Electrode and temperature sensor in the solution.

6.0.6 Select conductivity mode by pressing ‘MODE’ key and later by pressing Enter key. Enter the actual cell constant. Press Enter. Select calibration mode by pressing the appropriate key. Enter the conductivity value of standard solution and press Enter. Adjust the temperature, if necessary, and while maintaining it at 25 + 1°C begins vigorously agitating the standard solution, while periodically observing the conductivity. When the change in conductivity (due to uptake of atmospheric carbon dioxide) is less than a net of 0.1μs/cm per 5 minutes, press Enter. Thus the instrument is calibrated.

6.0.7 Cross check the calibration by checking the conductivity of known standard solutions in the measurement mode.

6.0.8 Solutions to be used for Quarterly calibration prepared given below:

6.0.9 147 μS solutions (0.001 M) : Dissolve 0.007455 g of Potassium Chloride (KCl) in 100 ml purified water.

6.0.10 1413 μS solutions (0.01 M) : Dissolve 0.07455 g of Potassium Chloride (KCl) in 100 ml purified water.

6.0.11 12,880 μS solutions (0. 1 M) : Dissolve 0. 7455 g of Potassium Chloride (KCl) in 100 ml purified water.

**Acceptance Criteria:**

|  |  |  |
| --- | --- | --- |
| Sr. No. | Solutions to be used for Quarterly calibration | Limits (μS) |
| 1.0 | 147 μS | 145.53 – 148.47 |
| 2.0 | 1413 μS | 1398.87-1427.13 |
| 3.0 | 12880 μS | 12751.2 - 13008.8 |

**Note:** The standard solution of the least conductivity should be calibrated first followed by the standard solutions in the increasing order of their conductivities. After each calibration, the electrode is to be rinsed thoroughly with purified water and wiped with a clean tissue.

6.0.12 To maintain the temperature of the conductivity solution, place it in an ice bath.

6.0.13 Discard the disposed conductivity solution after the calibration / verification.

6.0.14 Record the calibration data as per XYZ/CQA/SOP-070/FR-02 Appendix II (Page 1 of 2).

**6.1 Daily Verification of Conductivity Meter:**

6.1.2 For the verification, determine the conductivity of the following standard solutions by following the same procedure as specified under basic operation.

The verification is to be done on daily basis before using the instrument.

|  |  |  |
| --- | --- | --- |
| Sr. No. | Solutions to be used for verification | Limits |
| 1.0 | 5 μS | 4.9 - 5.1 |
| 2.0 | 10 μS | 9.9 - 10.1 |

Note:For 5μS and 10μS solution use NIST traceable conductivity standards. For the other standard solutions NIST traceable conductivity standards can be used.

6.1.3 Record the verification data as per XYZ/CQA/SOP-070/FR-03, Appendix III (Page 2 of 2)

6.1.4 Report any discrepancy observed during operation and calibration of instrument to Section

In charge or his representative for corrective and preventative action as per SOP No. XYZ/CQA/SOP-030, CAPA.

6.1.5 Section In charge or his representative will take the necessary action and report the same to Manager-Quality Assurance.

6.1.6 Affix “Out of Order” label on the instrument as per SOP No. XYZ/CQA/SOP-006, Labelling Policy.

**7.0 GENERATION OF INSTRUMENT CALIBRATION NUMBER**

Generate the instrument calibration number on calibration data sheet as INSCALXXYYZZZ where INS denotes instrument, CAL denotes calibration, XX denotes year, YY denotes month and ZZZ denotes sequence number.

# 8.0 ABBREVIATION

XYZ Xyz Pharmaceuticals Limited

SOP Standard Operating Procedure

QC Quality Control

CQA Corporate Quality Assurance

**APPENDIX I XYZ/CQA/SOP-070/FR-01**

**LOGBOOK FOR CONDUCTIVITY METER**

Instrument Id.: -------------------------

Location: -------------------------

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sr.No. | Date | Start Time | Name of the Sample | Batch No. / A. R. No. | End Time | Done By | Checked By | Remarks |
|  |  |  |  |  |  |  |  |  |
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**APPENDIX II XYZ/CQA/SOP-070/FR-02**

**CALIBRATION DATA SHEET INSCAL- --------------------------**

**Page 1 of 1**

**1.0 Instrument Id: -----------------------------------------------------------------**

**2.0 Location: -----------------------------------------------------------------------**

**3.0 Calibration Frequency: Quarterly**

**4.0 Calibration Date: -------------------------------------------------------------**

**5.0 Next Due Date: ---------------------------------------------------------------**

6.0 Observations

6.1 Solution (1) conductivity 84 μs/cm (Standard No :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

6.2 Solution (2) conductivity 147 μs/cm (Standard No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

6.3 Solution (3) conductivity 1413 μs/cm (Standard No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

6.4 Solution (4) conductivity 12880 μs/cm (Standard No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Cell Constant  (K) | Actual Cell constant (K) | Observed Cell Constant + 2 % of the Actual cell constant | Conductivity of the standards at 25 0 C (μS) | Observed Conductivity  ( + 1 % of the stated value) |
| 1.0 |  |  | 147 | at °C |
| 1.0 |  |  | 1413 | at °C |
| 1.0 |  |  | 12880 | at °C |

Remarks: The above parameters used for the calibration as per predefined acceptance criteria complies / Does not comply hence the instrument is suitable / Not suitable for routine analysis.

Done By: Checked By: Approved By:

Date: Date: Date:

**APPENDIX III XYZ/CQA /SOP-070/FR-03**

**Page 1of 1**

**DAILY VERIFICATION DATA SHEET**

1.0 Solution (5) conductivity 5 μs/cm (Standard No. : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )

2.0 Solution (6) conductivity 10 μs/cm (Standard No. : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )

3.0 Observations

|  |  |  |  |
| --- | --- | --- | --- |
| Cell Constant  (K) | Temperature of the standard solution | Conductivity of the standards at 25 0 C (μS) | Observed Conductivity  ( + 1 % of the stated value) |
| 0.1 |  | 5 |  |
| 0.1 |  | 10 |  |

Remarks: The above parameters used for the calibration as per predefined acceptance criteria complies / Does not comply hence the instrument is suitable / Not suitable for routine analysis.

Done By: Checked By: Approved By:

Date: Date: Date: