



Biopharmaceutical Development Program

Standard Operating Procedure

Title: **Standardization, Operation, and Maintenance of the Amber Science Model 2052, and 4081 Conductivity Meters**

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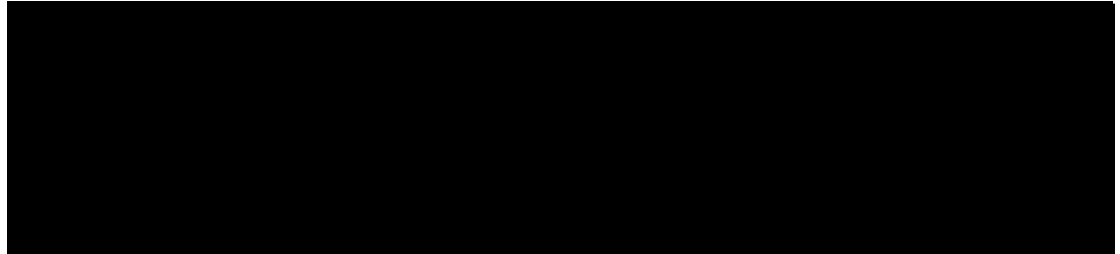


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1.0 Purpose

This procedure describes the operation of the Amber Science Model 2052, and 4081 Conductivity Meters

2.0 Scope

This SOP applies to Biopharmaceutical Development Program (BOP) personnel who operate the Amber Science Model 2052 or 4081 Conductivity Meter.

3.0 Authority and Responsibility

- 3.1 The Associate Director, Late Process Sciences, BOP has the authority to define this procedure.
- 3.2 The Associate Director, Late Process Sciences, BOP is responsible for training personnel in the procedure and for documenting this training to Biopharmaceutical Quality Assurance (BOA).

- 3.3 The Associate Director, Late Process Sciences, BDP is responsible for the implementation of this procedure.
- 3.4 BDP personnel are responsible for performing operations in compliance with this SOP.
- 3.5 BQA is responsible for quality oversight of this procedure.

4.0 Materials and Equipment

- 4.1 Amber Science Conductivity Meter Model 2052, or 4081.
- 4.2 15 mL Centrifuge tubes BDP PN 20006 or BDP approved equivalent.
- 4.3 Conductivity Standards as required for measured range:
 - 100 uS/cm, BDP PN 30026.
 - 1000 uS/cm, BDP PN 30025.
 - 10,000 uS/cm, BDP PN 30024.
 - 100,000 uS/cm, BDP PN 30023
- 4.4 Replacement Conductivity Cell:
 - BDP PN 21388, best for use below 2,000 micro Siemens.
 - BDP PN 22078, best for use above 2,000 micro Siemens.
 - BDP PN 21934, best for use below 2,000 micro Siemens.

5.0 Standardization

- 5.1 Standardization Guidelines
 - 5.1.1 Standardize the meter once per day whenever it is used for collecting process data.
 - 5.1.2 Standardize the meter with standards bracketing the conductivities of the samples being measured.
 - 5.1.3 Obtain the standards for the same manufacturer.
 - 5.1.4 Keep the standardization solutions at temperatures between 20°C and 30°C.
- 5.2 Standardization Procedure
 - 5.2.1 Connect the conductivity cell to the meter.
 - 5.2.2 **For model 2052**, turn the function switch to ATC on position.
For model 4081, power on the unit, allow the self-test to finish. Do not use the meter and contact the Supervisor if the self-test fails. If conductivity is not already selected, press the Function key until Conductivity is selected.
 - 5.2.3 Obtain the standard solution(s) for the range being measured (0-100, 100-1000, 1000-10000 or 10000 –100000 uS/cm).
 - 5.2.4 Place 8-9 mL of the standard solution corresponding to the high end of the range in each of the two 15 mL centrifuge tubes and 4-5 mL in a third tube.
 - 5.2.5 Rinse the cell with WFI.

- 5.2.6 Dip the cell in one of the tubes containing 8-9 mL of solution and move up and down to rinse the cell with the standard solution. Select the lowest range that will provide a reading. Withdraw the cell from the tube and gently shake off residual liquid. Do not wipe off the cell. Repeat using the second tube containing 8-9 mL of standard solution.
- 5.2.7 Dip the cell in the third tube containing 4-5 mL of standard solution.
- 5.2.8 When the reading stabilizes, adjust the meter reading to the assigned value of the standard solution as follows, and record the value as meter reading for standard #1.
- 5.2.8.1 **Model 2052** Adjust the master calibration control set screw.
- Turn the function switch to the self-check position, and turn the range switch to the B position. If the meter reading is not between 8.9 and 11.1, replace the cell and repeat standardization procedure.
- 5.2.8.2 **Model 4081** Press the calibrate button (*). Use the \wedge , \vee buttons to adjust the cell constant. Press the calibrate button (*) to save the setting.
- Press the function button until *Self-Test* appears. Allow the reading to stabilize. If the cell constant is not between 8.9 and 11.1, replace the cell and repeat standardization procedure.
- 5.2.9 Record the Cell Constant Value on Form 12127-01.
- 5.2.10** Turn the function switch back to ATC on position for the **2052**, or press Function until you return to *Conductivity* for the **4081**.
- 5.2.11 Check the meter at the lower end of the standardization range as follows.
- 5.2.11.1 If the range is from 100-1000, 1000-10000 or 10000-100000 uS/cm, repeat steps 3.2.4 through 3.2.7 using the standard solution corresponding to the lower end of the standardization range. Record the low end reading as meter reading for standard #2. Consult chart below to confirm that the low end reading is within specification. If reading is not within the guidelines, consult the Supervisor and do not use meter until it has been successfully standardized.
- 5.2.11.2
- | Range | Full Scale | Acceptable Range Within | Resolution |
|-------|------------|-------------------------|------------|
| A | 2.000 uS | 0.004 uS | .001 uS |
| B | 20.00 uS | 0.03 uS | .01 uS |
| C | 200.0 uS | 0.2 uS | .1 uS |
| D | 2.00 mS | 0.002mS | .001 mS |
| E | 20.00 mS | 0.03 mS | .01 mS |
| F | 200.0 mS | 0.6 mS | .1 mS |
- 5.2.11.3 If the range is from 0-100 uS/, air will be used as the low end standard. The conductivity of air is 0 uS/. Rinse the cell with high

purity water and shake out the residual liquid in the cell and confirm that the reading is $< 0.004 \text{ uS/(uS)}$. If the value is outside of the range, do not use the meter and consult with the Supervisor.

6.0 Operation

6.1 For model 2052, turn the function switch to ATC on position.

For model 4081, press the Function key until *Conductivity* is selected.

NOTE: When using model 4081 to test for the release of the Penn-Tech vial washer turn off the Automatic Temperature Compensation (ATC) function by pressing the Parameter key and changing the TEMP COEF to .00%. ATC will then be turned off. The unit will default back to original settings (ATC on) when power is turned off.

6.2 Conductivity measurement may interfere with other electrical current based measurement such as pH. Do not measure at the same time with the same solution.

6.3 Place 8-9 mL of the unknown sample into each of two 15 mL centrifuge tubes and 4-5 mL in a third tube.

6.4 Rinse the cell with high purity water.

6.5 Dip the cell in one of the tubes containing 8-9 mL of sample and move the cell up and down to rinse the cell with the sample. Select the lowest range that will provide a reading. Withdraw the cell from the tube and gently shake off the residual liquid. Do not wipe off the cell. Repeat using the second tube containing 8-9 mL of sample.

6.6 Dip the cell in the third tube containing 4-5 mL of sample. As soon as the reading stabilizes, record the reading where requested on the Batch Production Record.

6.7 Rinse the cell with high purity water. Turn off the power to the meter when it is not in use. Store the cell dry.

7.0 Maintenance

7.1 Replace the conductivity cell when the desired linear range cannot be demonstrated or when the cell constant falls outside of the range specified in 3.2.8.

7.2 The battery (standard 9 volt) must be replaced whenever the "LoBatt" indicator is lit.

8.0 Documentation

8.1 Documentation of this procedure must be made on Form 12127-01 in a logbook and on the batch production records where requested.

8.2 Record all usage, cleaning and maintenance of this equipment in the specific equipment logbook, as per **SOP 21533 - Equipment/Facilities Logbooks**.

9.0 Attachments

9.1 **Attachment 1** Conductivity Meter Standardization and Use

Attachment 1**Conductivity Meter Standardization and Use**

NCI-Frederick
Form No.: 12127-01
SOP No.: 12127
Revision 04: NOV 17 2015

Conductivity Meter Standardization and Use

Instrument ID: _____

Standard	Value	BDP PN	BDP Lot Number	Expiration
1				
2				

Cell Constant: (Allowable range 8.9 – 11.1)	
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Standard	Meter Reading	Standard Value	Difference	Acceptable Yes/No
1				
2				

Allowable Difference:	Range	Allowable Difference
	A	0.004 (uS)
	B	0.03 (uS)
	C	0.2 (uS)
	D	0.002 (mS)
	E	0.03 (mS)
	F	0.6 (mS)

Standardization Performed By/Date: _____

Activity/Comments	Initials/Date

Reviewed By/Date: _____