



Biopharmaceutical Development Program

Standard Operating Procedure

Title: Hach Total Hardness Test Kit

SOP Number: 22707

Revision Number: 03

Supersedes: Revision 02

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Originator/Date:

Approval/Date:

Approval/Date:

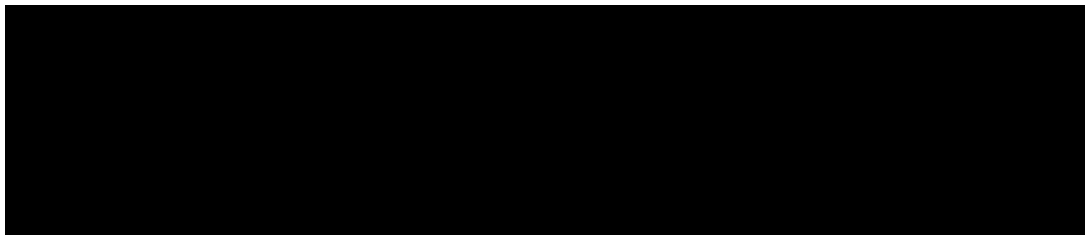


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1.0 Purpose

The purpose of this SOP is to outline the procedure for measuring hardness in water.

2.0 Scope

The Process Analytics Laboratory will perform this procedure.

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics (PA) has the authority to define this procedure.
- 3.2 The Director, PA is responsible for assignment of this procedure, accessing of personnel, and documenting that this training as occurred.
- 3.3 PA personnel are responsible for the performance of this procedure.

- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Materials

- 4.1 Hach total hardness test kit Ha-71A, Catalog number 1452-01.
- 4.2 Buffer Solution Hardness 1, BDP PN 30456.
- 4.3 Titrant Solution, BDP PN 30457.
- 4.4 Manver Hardness Indication, BDP PN 30458.

5.0 Procedure

5.1 Low Range Hardness Test

- 5.1.1 Fill the Erlenmeyer flask provided to the 100 mL mark with the water to be tested.
- 5.1.2 Add two droppers full of the Buffer Solution, Hardness 1, to the flask and swirl to mix.
- 5.1.3 Add four drops of ManVer 2 Hardness Indicator, Hardness 2, to the flask and swirl to mix. A blue color indicates soft water. If a red color develops proceed to step 5.1.4.
- 5.1.4 Add Titrant Solution, Hardness 3, drop by drop to the flask, swirling constantly as the drops are added. Count each drop as it is added, and continue to add reagent until the color changes from red to blue.
- 5.1.5 Each drop of the Titrant Reagent, Hardness 3, used to bring about the color change is equal to 1 mg/mL as calcium carbonate.

5.2 High Range Hardness Test

- 5.2.1 Fill the plastic measuring tube level full with the water to be tested. Pour the contents of the tube into the mixing bottle.
- 5.2.2 Add three drops of the buffer solution, Hardness 1, to the mixing bottle.
- 5.2.3 Add one drop of ManVer 2 Hardness Indicator, Hardness Two, to the mixing bottle and swirl to mix. A blue color indicates soft water. If red color develops, proceed to step 5.2.4.
- 5.2.4 Add Titrant Reagent, Hardness 3, drop-by-drop to the bottle, swirl the bottle constantly as the drops are added. Count each drop as it is added, and continue to add reagent until the color changes from red to blue.
- 5.2.5 Each drop of Titrant Reagent, Hardness 3, used to bring about the color change is equal to 17.1 mg/L hardness expressed as calcium carbonate.

6.0 Documentation

- 6.1 The test results are stored in BQA's archives for at least 10 years.
- 6.2 Record the test results on Form 22707-01 (Attachment 1).

7.0 Attachments

- 7.1 **Attachment 1** Form 22702-01, Total Hardness

Attachment 1

NCI-Frederick
Form No.: 22707-01
SOP No.: 22707
Revision 03:

Total Hardness

Reagent
Lot #: _____
Expiration Date: _____

Reagent
Lot #: _____
Expiration Date: _____

Reagent
Lot #: _____
Expiration Date: _____

QC #	Sample ID	Result	Analyst/Date

Comments: _____

Reviewed By: _____ Date: _____