



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Hach Total Hardness Test Kit

SOP Number: 22707

Revision: 04

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1. PURPOSE

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

2. SCOPE

This procedure applies to the process analytics laboratory testing of water.

3. RESPONSIBILITIES

3.1 Director / Process Analytics (PA)

- Defines this procedure.
- Provides training to personnel.

3.2 Personnel / PA

- Performs this procedure.

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

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4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
31471	Hach Total Hardness Test Kit Ha-71A	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30456	Buffer Solution Hardness	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30457	Titration Solution	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30458	Manver Hardness Indication	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5. PROCEDURE

5.1 Low Range Hardness Test

- 5.1.1 Additional steps 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 Titration 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 Titration 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 of 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.

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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. DOCUMENTATION AND RECORDS

6.1 The test results are stored in BQAD's archives for at least 10 years.

6.2 Record the test results on **Form 22707-01**.

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22707-01	Total Hardness