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**1.0 Purpose**

This SOP describes how to test water for the presence of calcium by Current USP official monograph method for Sterile Purified Water.

**2.0 Scope**

This SOP will be performed by PA personnel to determine the presence of calcium in water.

**3.0 Authority and Responsibility**

3.1 The Director of Process Analytics (PA) has the authority to define this procedure.

3.2 The Supervisor of Process Analytics (PA) is responsible for assignment of this procedure.

3.3 PA Laboratory personnel are responsible for the safe performance of this procedure. PA laboratory personnel are responsible for reading the Material Safety Data Sheets (MSDS) for reagents and materials to be tested.

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

**4.0 Equipment and Reagents**

4.1 Color comparison tubes.

4.2 Ammonium Oxalate monohydrate, BDP PN 30418, or BDP approved equivalent.

4.3 Rack for color comparison tubes.

4.4 Pipet.

4.5 100 mL volumetric flask.

**5.0 Preparation and Precautions**

5.1 Safety glasses, lab coats, and gloves are required for this procedure.



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5.2 The color comparison tube must be rinsed thoroughly with Purified water after each test sample. Contamination from previous tests may cause errors in subsequent tests.

5.3 Ammonium Oxalate Test Solution (TS): prepare the solution by dissolving 3.5 grams of Ammonium Oxalate monohydrate into 70-80 mL purified water. Add to 100 mL volumetric and bring up to 100 mL with purified water.

#### 6.0 Calcium Test

6.1 Rinse the color comparison tube(s) thoroughly with the water to be tested. Add 100 mL of the water sample to the tube.

6.2 Add 2 mL of Ammonium Oxalate TS.

6.3 Place all tubes in the rack and tip the rack to view directly down the comparison tube.

6.4 If no turbidity is produced, the test sample passes.

#### 7.0 Documentation

7.1 Record reagent lot numbers and test results into the PA Lab book for Raw Materials.

7.2 Report result as PASS or FAIL.

7.3 Record results, lab book number, and page number on the Raw Material Test Report, Form 22714-01 as per **SOP 22714, *Sampling, Testing, and Review of CGMP Materials by BQC.***

#### 8.0 References and Related Documents

**SOP 22714**     *Sampling, Testing, and Review of CGMP Materials by BQC*