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1.0 Purpose

This procedure describes how to test water for the presence of carbon dioxide by the Current USP official monograph method for sterile, water for injection.

2.0 Scope

This procedure will be performed by Process Analytics personnel to determine the presence of carbon dioxide.

3.0 Authority and Responsibility

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

3.2 PA is responsible for training laboratory personnel.

3.3 PA personnel are responsible for the accurate performance of this procedure.

3.4 PA is responsible for reviewing the data and documentation of the results of this procedure.

3.5 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this operation.

4.0 Equipment and Reagents

4.1 Color comparison tubes, graduated.

4.2 Calcium Hydroxide, USP, BDP PN 30414 or BDP approved equivalent.

4.3 Tube Rack for color comparison tubes.

4.4 25 mL transfer pipets.

4.5 1L volumetric flask.

4.6 Magnetic Stirrer.

5.0 Preparations and Precautions

5.1 Color comparison tube must be rinsed thoroughly with Purified Water after each test sample. Contamination from previous test may cause errors in subsequent tests.

5.2 Calcium Hydroxide TS: Prepare the solution by dissolving 3 g of calcium hydroxide into 1 L of Purified Water in a 1L volumetric flask. Mix completely with a magnetic stir bar on a magnetic stirrer for 1 hour, and then allow mixture to stand undisturbed for 1 day. Dispense only the clear supernatant.

6.0 Carbon Dioxide Test

6.1 Rinse the color comparison tube(s) thoroughly with the water to be tested. Add 25 mL of the water to be tested to the tube.

6.2 Add 25 mL of the calcium Hydroxide Test Solution (TS) to each tube with transfer pipet.

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

6.4 If no turbidity is produced, test sample passes.

7.0 Documentation

7.1 Record QC test number and description of test article, test performed, name of reagent(s), BDP number, expiration date, test preparations, results, initials, and date of test in the laboratory notebook for quality control of raw materials.

7.2 Record the test result on the QC Form 22714-01, Raw Material Sample and Test Report Form, per **SOP 22714, *Sampling, Testing, and Review of CGMP Materials by Process Analytic / Quality Control***, accompanying the test request and reference the laboratory notebook and page number.

8.0 References and Related Documents

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

Current USP <Sterile Water for Injection> Monograph.

9.0 Change Summary

[redacted]