Standard Operating Procedure

Title: Test for the Presence of Oxidizable Substances in Water

SOP Number: 22152 **Revision Number: 02**

Supersedes: Revision 01 **Effective Date: SEP 15 2011**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This SOP describes how to test water for the presence of oxidizable substances.

2.0 Scope

This SOP applies to Process Analytics personnel who are trained to perform this procedure.

3.0 Authority and Responsibility

3.1 The Director of 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 procedure.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

4.0 Equipment and Reagents

4.1 Beaker, 150 mL, Pyrex graduated.

4.2 Sulfuric Acid, 2.0 Normal, BDP PN 30030, or BDP approved equivalent.

4.3 Potassium Permanganate, BDP PN 30417, or BDP approved equivalent. The user will have to make a 0.02 M solution from the powder.

4.4 Pipette

4.5 Graduated Cylinder, 10 mL, calibrated To Deliver (TD) Class A.

4.6 Graduated Cylinder, 100 mL, calibrated To Deliver (TD) Class A.

4.7 Glass Beads, perforated, 4 mm.

4.8 Pipette tips, 20-250 mL, BDP PN 20385, or BDP approved equivalent.

4.9 Corning Hotplate

5.0 Preparations and Precautions

5.1 All manipulations are performed in a Chemical Fume Hood.

5.2 Several perforated glass beads are added to each test beaker to promote gentle, efficient boiling and to minimize “bumping” during the test period.

6.0 Oxidizable Substance Test

6.1 Label and rinse each beaker to be used thoroughly with the water sample to be tested. Fill a clean 100 mL graduated cylinder to the 100 mL mark with the water sample. Add two or three clean glass beads to each beaker.

6.2 Use a 10 mL graduated cylinder to add 10 mL of 2.0 N sulfuric acid to each beaker.

6.3 Heat the sample to boiling; pipet 0.2 mL of 0.02M potassium permanganate solutions to each beaker and boil the sample for 5 minutes.

6.4 If pink color does not completely disappear, the test sample passes.

6.5 Report the result as PASS or FAIL.

7.0 Documentation

7.1 Record QC test number and description of test article; test performed, name of reagents, 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 Test Form, per **SOP 22714, *Sampling, Testing, and Review of CGMP Materials by BQC*,** accompanying the test request and reference the laboratory notebook and page number. Record test results on the test request form if appropriate.

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8.0 References and Related Documents

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

8.2 Current USP <Sterile Purified Water>.

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