Biopharmaceutical Development Program

Standard Operating Procedure

Title: Performance of the Thermal Downshock Test

SOP Number: 22715 **Revision Number: 03**

Supersedes: Revision 02 **Effective Date: SEP 15 2011**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

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1.0 Purpose

This procedure describes the performance of the thermal downshock test to reveal the presence of flaws and initiate vial breakage of those vials that have flaws.

2.0 Scope

This procedure applies to BDP Manufacturing and Process Analytics personnel involved in preparing the testing vials for glass flaws.

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 and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 PA and BDP Manufacturing personnel are responsible for the performance of this procedure.

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

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3.5 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

4.1 BDP Manufacturing Personnel

4.1.1 After the dimensional tests and the polarimetric test are completed, PA personnel will give the vials to BDP Production personnel. BDP Production will fill the vials with Milli-Q water to 40% of the total volume, (i.e., place 1.25 mL of water into a 3 mL vial) The number of vials to be tested is determined in **SOP 22714, *Sampling, Testing, and Review of CGMP Materials by BQC***.

4.1.2 Stopper and crimp each vial with a crimper.

4.1.3 Once all of the vials are sealed, place the vials on a stainless steel tray and freeze at ≤ -70°C.

4.2 PA Personnel

4.2.1 After the vials have spent at least 24 hours at ≤-70°C, visually examine each vial for cracks and breakage.

4.2.2 Allow the vials to thaw at room temperature and visually examine each vial for cracks and breakage as specified on the specification sheet.

4.2.3 The lot conforms to specifications if less than the appropriate number of vials break or contain cracks as specified on the specification sheet.

4.2.4 Record pass or fail on Form 22714-01, Raw Material Test Report.

5.0 References and Related Documents

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

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