



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Performance of the Thermal Downshock Test
SOP Number: 22715
Revision: 04

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1. 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. SCOPE

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

3. RESPONSIBILITIES

- 3.1 Director / Process Analytics (PA)
 - Defines procedure
- 3.2 Process Analytics (PA)
 - Trains laboratory personnel
 - Reviews data
- 3.3 PA and BDP Manufacturing personnel
 - Performs procedure
- 3.4 Biopharmaceutical Quality Assurance (BQA)
 - Provides quality oversight

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4. 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 Type 1 or better 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 $\leq -70^{\circ}\text{C}$.

4.2 PA Personnel

4.2.1 After the vials have spent at least 24 hours at $\leq -70^{\circ}\text{C}$, 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. REFERENCES AND RELATED DOCUMENTS

| Document Number | Title |
|-----------------|--|
| 22714 | Sampling, Testing, and Review of CGMP Materials by BQC |
| 22714-01 | Raw Material Test Report |