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1.0 Purpose

This SOP describes the incubation procedures of Biological Indicators (BI) to determine the efficacy of sterilization cycles.

2.0 Scope

This procedure applies to Process Analytics personnel who will perform incubation procedures.

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

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

3.4 BQA is responsible for quality oversight of this operation.

4.0 Biological Indicators (BI) Incubation

4.1 The requestor will submit BI's and controls to PA for incubation.

4.2 BI's are incubated according to the manufacturer's recommendations for temperature. The incubation duration is at minimum the Manufacturer's recommendations. This allows for prolonged incubation over non-working days, i.e., weekends, holidays, etc.

4.3 After BI's have been processed, samples must be submitted to PA for incubation within 4 hours.

5.0 BI Controls

5.1 The requestor must submit at least one positive control and one negative control for each testing series.

5.2 An untreated ampule shall serve as a positive control, and an ampule without spores will serve as a negative control.

5.3 Incubate controls at the same temperature and duration as the test BI's, refer to the manufacturer's recommendations.

6.0 BI Interpretation

6.0 Observe the BI's each working day during the incubation period. The presence of turbidity and/or a color change to yellow indicates bacterial growth, presumably due to the spores having survived the sterilization process.

6.1 The positive control shall exhibit growth, yellow color, for the test to be acceptable. If no growth occurs, purple color, the sterilization cycle is not valid and must be repeated.

6.2 The negative control shall not exhibit growth for the test to be acceptable. If growth occurs, the test is not valid.

7.0 Documentation

7.0 Record observations from each day on the Biological Indicators Form and attach the form to the QC Test Request form.

7.1 Submit completed forms for PA and BQA review.

8.0 References and Related Documents

Form 22948-01 *Biological Indicator Form*

9.0 Change Summary

[redacted]