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1.0 Purpose

This procedure describes how to heat inactivate serum.

2.0 Scope

This SOP applies to BDP personnel who heat inactivate serum.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 Production personnel are responsible for the implementation of this procedure.

3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Procedure

Refer to **SOP 13227, Use and Maintenance of the Precision Scientific Model 183/188 Water Baths.**

4.1 Thaw serum at 2 to 8°C just until serum is thawed.

4.2 Fill the water bath with WFI water to about 1/4" above the serum line in the bottle.

4.3 Preheat the water bath to the desired temperature for heat inactivation (56°C ± 1°C and 65°C ± 1°C are used dependent on the request).



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- 4.4 Mix the serum well by swirling before heat inactivation. Assure that no protein is still on the bottom of the bottle or not blended.
 - 4.5 Place the serum into the water bath. Place a bottle of water that is the same size and temperature as the serum bottle in the water bath with a thermometer inside to monitor the temperature of the serum. Place the lid on the water bath. When the temperatures of the water bath and the bottles are equilibrated, begin timing for a minimum of 30 minutes.
 - 4.6 When the 30-minute period is over, remove the serum from the water bath. Label the serum with the heat inactivated temperature, the amount of time for heat inactivation, the date, and the initials of the person performing the heat inactivation. When the procedure is completed, store the serum in the refrigerator at 2 to 8°C.

5.0 Documentation

- 5.1 Document heat inactivation on Form 13221-01, Heat Inactivation Logsheet, Attachment 1.
- 5.2 Document serum heat inactivation in the Batch Production Record or laboratory notebook as appropriate.

6.0 References and Related Documents

- 6.1 **SOP 13227** *Use and Maintenance of the Precision Scientific Model 183/188 Water*
- 6.2 **Form 13221-01** *Serum Heat Inactivation Logsheet*

7.0 Change Summary

