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PHARMACY PRODUCTS
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Depyrogenation

Per USP Chapter <797> dry heat depyrogenation must be used to render glassware or containers, such as vials free from pyrogens and viable microbes. The description of cycle and duration must be documented in the facility. Also, the effectiveness of the cycle must be verified using endotoxin challenge vials (ECVs) achieving a three-log reduction in endotoxin. The typical cycle is 250°C for 30 minutes with an acceptable range in temperature in the empty chamber of ±15° when the unit is operating at not less than 250°C.

ECVs are available from many sources. If endotoxin testing is cannot be performed in the facility, many third party laboratories will perform the test. Typical ECVs kits contain as many as 25 vials, permitting the testing of multiple points throughout the oven or enough to perform the test in larger ovens.

A minimum of 5 points in the oven should be tested, each corner and the middle. The more areas, or in the case of larger ovens, the more levels sampled the better. Typically a minimum of 2 control vials should be tested to permit calculation of an average and calculation of the three-log reduction.

The USP also states that since depyrogenation is a more rigorous challenge for dry-heat processing systems than for biological indicator inactivation, it is generally not necessary to include BIs when validating dry-heat processes if validation of depyrogenation is demonstrated. The fact that a three-log cycle reduction or greater is achieved demonstrates not only depyrogenation but also sterilization.

Per USP <797>, to achieve sterility and depyrogenation, glass and metal devices can be covered tightly with aluminum foil, and then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes. These items are then to be used immediately or stored until use in an environment suitable for compounding *Low-Risk Level CSPs* and *Medium-Risk Level CSPs*.

References:
USP Chapter <797> and Chapter <1211> from

Thermo Scientific™ Heratherm™
General Protocol Oven – Catalog No. 417-10034