



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Preparation of Supplies for Dry Heat (Oven) Sterilization / Depyrogenation
SOP Number: 19405
Revision: 04

TABLE OF CONTENTS

1. PURPOSE	1
2. SCOPE	1
3. RESPONSIBILITIES	1
4. MATERIALS AND REAGENTS.....	2
5. EQUIPMENT	2
6. PROCEDURE.....	2
7. DOCUMENTATION AND RECORDS.....	3
8. REFERENCES AND RELATED DOCUMENTS.....	3

1. PURPOSE

This procedure describes general practices for the preparation of equipment/supplies to be dry heat sterilized.

2. SCOPE

This procedure defines general principles governing the preparation and dry heat sterilization of equipment/supplies to be used for CGMP applications in the ATRF.

3. RESPONSIBILITIES

3.1 The Manager, Technical Operations, Late Process Sciences, Biopharmaceutical Development Program (BDP)

- Defines the procedure.

3.2 BDP manufacturing personnel

- Performs the procedure.

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

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4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
20719	Aluminum foil, only use all-foil aluminum as this product is oil-free.	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
N/A	High temperature oven tape.	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5. EQUIPMENT

- TPS Oven, BDP #OVEN-003A.

6. PROCEDURE

6.1 General Preparation

- 6.1.1 Materials to be dry heat sterilized must be compatible with temperatures of approximately 275°C for time periods of up to 8 hours.
- 6.1.2 Load configurations and oven cycles must be in accordance with the "Performance Qualification Protocol" for BDP #OVEN-003A.
- 6.1.3 Wrapping is to be performed so as to provide a significant barrier to microbial contamination of critical surfaces during storage.
- 6.1.4 Items must be marked with a permanent marker on the outer wrap as follows to provide traceability.
- 6.1.4.1 Date of run
- 6.1.4.2 Identification
- 6.1.5 Equipment/supplies that are to move from a "dirty" area to a "clean" area after dry heat sterilization are wrapped as specified in SOP 19415 - Transport of Sterilized Materials in the ATRF.
- 6.1.6 Specific requirements for preparation of equipment/supplies may be added to the above requirements on an as-needed basis.



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6.2 Preparation of Glass Vials

6.2.1 Miscellaneous vials (weight check, etc.) are wrapped in aluminum foil.

6.2.2 Vials, which have been racked into stainless steel pans, will have the pans wrapped in aluminum foil and the edges of the foil sealed shut with high temperature oven tape.

6.3 Preparation of Miscellaneous Supplies

Each individual piece will be wrapped in aluminum foil.

7. DOCUMENTATION AND RECORDS

7.1 Record the contents of each oven load in the oven logbook as specified in SOP 15146 - Operation and Maintenance of the TPS Depyrogenation Oven.

7.2 Upon completion of the oven cycle, the chart record is reviewed by the operator to determine acceptability based on established cycle parameters specified in SOP 15146 - Operation and Maintenance of the TPS Depyrogenation Oven. If the cycle is unacceptable, notify the Supervisor immediately.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
15146	Operations and Maintenance of the TPS Depyrogenation Oven.
19415	Transport of Sterilized Materials in the ATRF.