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Validation of Dry Heat Processes Used for Depyrogenation and Sterilization

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PDA Validation of Dry Heat Processes Used for Depyrogenation and Sterilization Technical Report Team

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Table of Contents

<p>1.0 INTRODUCTION 1</p> <p> 1.1 Purpose and Scope 1</p> <p>2.0 GLOSSARY OF TERMS 2</p> <p>3.0 THE SCIENCE OF DRY HEAT DEPYROGENATION AND STERILIZATION 6</p> <p> 3.1 Depyrogenation 6</p> <p> 3.2 Endotoxin Indicators..... 7</p> <p> 3.2.1 Preparation and Inoculation 7</p> <p> 3.2.2 Sample Processing 7</p> <p> 3.2.3 Recovery 8</p> <p> 3.2.4 Results Interpretation/Endotoxin Log Reduction Calculations 8</p> <p> 3.2.5 Glassware Depyrogenation 8</p> <p> 3.2.6 F_H-value for Depyrogenation 9</p> <p> 3.3 Sterilization 9</p> <p> 3.3.1 Mechanisms of Inactivation 9</p> <p> 3.3.1.1 F_H-Value for Sterilization 10</p> <p> 3.3.1.2 D-value and z-value 11</p> <p> 3.3.2 Biological Indicators 11</p> <p> 3.3.2.1 Biological Indicator Selection and Type of Carrier 11</p> <p>4.0 EQUIPMENT DESIGN..... 13</p> <p> 4.1 User Requirements Specification 13</p> <p> 4.1.1 High-efficiency Particulate Air or Ultralow Particulate Air Filters 13</p> <p> 4.1.2 Batch Convection Oven 14</p> <p> 4.1.3 Continuous Convection Tunnel..... 15</p> <p>5.0 EQUIPMENT QUALIFICATION 17</p> <p> 5.1 Environmental Qualification 18</p> <p> 5.2 Uniformity of Heating Media 18</p> <p> 5.3 Empty Chamber Temperature Distribution (Ovens and Tunnels) 19</p>	<p>6.0 PROCESS DEVELOPMENT 20</p> <p> 6.1 Process Design Approaches 20</p> <p> 6.1.1 Overkill Design Approach..... 20</p> <p> 6.1.2 Product Specific Design Approach 21</p> <p> 6.2 Defining Operating Parameters 21</p> <p> 6.3 Batch Oven Process Development 21</p> <p> 6.3.1 Developing Loading Patterns 21</p> <p> 6.3.2 Loaded Batch Oven Temperature Distribution Studies 22</p> <p> 6.3.3 Loaded Batch Oven Heat Penetration Studies 22</p> <p> 6.4 Continuous Convection Tunnel Process Development..... 23</p> <p> 6.4.1 Developing Loading Patterns – Continuous Tunnels..... 24</p> <p> 6.4.2 Loaded Tunnel Temperature Distribution 24</p> <p> 6.4.3 Loaded Tunnel Heat Penetration Studies 25</p> <p>7.0 PERFORMANCE QUALIFICATION..... 27</p> <p> 7.1 Physical Qualification 27</p> <p> 7.2 Biological Qualification 27</p> <p> 7.2.1 Biological Indicator Testing 27</p> <p> 7.2.2 Endotoxin Indicator Testing 28</p> <p> 7.3 Process Equivalency 28</p> <p> 8.1 Routine Release 29</p> <p> 8.2 Preventive Maintenance 29</p> <p>8.0 ONGOING PROCESS CONTROL 29</p> <p> 8.3 Change Control / Revalidation..... 30</p> <p> 8.4 Periodic Requalification of Equipment..... 30</p> <p> 8.5 Parametric Release 30</p> <p>9.0 REFERENCES 32</p>
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FIGURES AND TABLES INDEX

<p>Figure 4.1.2-1 Example of Batch Convection Oven Showing Airflow..... 15</p> <p>Figure 4.1.3-1 Continuous Convection Tunnel..... 16</p> <p>Table 5.0-1 Example of Equipment Qualification Checklist 17</p>	<p>Figure 6.3.3-1 Load Profile–Batch Oven 23</p> <p>Figure 6.4.3-1 Glass Vial Load Heat Penetration Profile–Continuous Convection Oven... 26</p>
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1.0 Introduction

This technical report is an update of PDA's *Technical Report No. 3, Validation of Dry Heat Processes used for Sterilization and Depyrogenation* which was issued in 1981. The technical report focuses on the microbiology and engineering qualification of dry-heat sterilization and depyrogenation processes and the general approach to sterilization and depyrogenation science in batch and continuous sterilizers (ovens and tunnels). This technical report is based on standard depyrogenation and sterilization science.

The primary objective of the Technical Report Team was to develop a scientific technical report on dry-heat depyrogenation and sterilization processes that provides recommendations for use by industry and regulators. References to appropriate and current scientific publications, international regulatory documents, journal articles, technical papers and books are used where more detail and supportive data can be found.

The Technical Report Team is composed of diverse international team of professionals to ensure the methods, terminology and practices of dry-heat depyrogenation and sterilization processes reflect sound science and can be used globally. This technical report was disseminated in draft for public review and comment prior to publication to ensure its suitability as a recommendation of best practices to industry.

1.1 Purpose and Scope

This technical report provides information to the manufacturers of pharmaceutical products for validating dry-heat depyrogenation and sterilization processes. The concepts and methods presented within this technical report are not intended to be a regulatory standard, but rather as points to be considered during the validation of dry-heat processes. Other technically equivalent methods may exist and may be used if they can be supported by sound scientific methods.

This technical report is intended to give information about current industry practices and approaches to validating dry-heat depyrogenation and sterilization processes. In addition, sections will cover various aspects of dry-heat sterilization using biological indicators.

This technical report is organized in a chronological fashion, starting with a discussion of the general concepts of depyrogenation and sterilization science which are the foundation upon which to build a robust process. This includes use of biological indicators and endotoxin indicators. Also included are points to consider in equipment design, equipment verification, process development and performance qualification for new systems and the development and validation of processes for existing systems.

In the discussion of process development, particular attention has been given to the load type, loading patterns, and temperature profiles for depyrogenation and sterilization in both ovens and tunnels. The sections are followed by a brief discussion of items for consideration during routine processing and ongoing maintenance of the validated process.

The background sections on depyrogenation/sterilization science and endotoxin/biological indicators are not comprehensive—but provide information specific to dry-heat processes. Information within the technical report is applicable to both forced hot air dry-heat batch processes (chambers) and to continuous processes (tunnels). Information within this technical report does not apply to dry-heat processes used for the sterilization of oil bases and oil based products, fixed processing streams or to those processes using infrared and microwave heating media.