Depyrogenation Study

DHO Step Removal

Confidential Client

PROJECT DESCRIPTION

This endotoxin reduction study was performed at the Hyde Analytical Laboratory using a Charles River MCS150 Endotoxin Analyzer and Getinge Life Science 910 LX Ultima parts washer.

Recovery of endotoxin indicator from glassware was evaluated following development of a spike and rinse method. The study was then scaled to larger glassware, and finally confirmed following cleaning in a parts washer using cycle parameters representative of full-scale. Confirmation was performed using several load configurations and two cycles.

Cycle development of the laboratory parts washer was performed prior to chemistry and load geometry confirmation, and included cycle parameter programming and spray coverage testing. Finally, the study was transferred to the client site for use in cleaning validation for glassware.

SCOPE AND DELIVERABLES

- Endotoxin Spiking Method Development
- Chemistry & Load Geometry Confirmation
- On-site Study Transfer
- Summary Report

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STUDY OVERVIEW

Dry heat ovens are commonly used for depyrogenation in pharmaceutical manufacturing, which is the process of removing pyrogens (usually endotoxins from bacterial cell walls) from equipment or packaging materials.

The ovens need to maintain a consistent temperature for extended periods, which can lead to relatively high energy usage.

To reduce energy consumption and better characterize cleaning steps, drug manufacturers may leverage endotoxin removal studies during cleaning validation.

Removal of the widely used DHO step has the potential to significantly improve environmental impact and save on costs.

Glassware used for storing bulk materials is cleaned within parts washers using a validated cleaning cycle, including a dry-heat oven depyrogenation step. This study was conducted to evaluate removal of endotoxin from glassware without the use of the DHO step.

Studies indicate sufficient endotoxin reduction is achieved without the use of the DHO step, demonstrating promise for site-wide removal of this step following formal parts washer validation at a large U.S. manufacturing site.

SOLUTIONS, RESULTS AND ACCOMPLISHMENTS

1. **Phase I:** Developed a spike and rinse method for recovery of endotoxin from glassware, including scalability testing using a range of endotoxin concentrations.
2. **Phase II:** Developed a spike and rinse method for recovery of endotoxin from glassware, including scalability testing using a range of endotoxin concentrations.
3. **Phase III:** Transferred the endotoxin recovery method to an on-site Hyde engineer for execution during parts washer validation.