POLARDRY® ELECTROSTATIC DRYING: ASEPTIC PROCESS

CASE STUDY

MAINTAINING STERILITY AND PREVENTING CONTAMINATION OF MATERIALS DURING THE POLARDRY® ELECTROSTATIC DRYING PROCESS

Maintaining sterility and/or preventing contamination is a crucial factor during pharmaceutical or biologics manufacturing. Two common ways to achieve aseptic manufacturing are to (a) include a final terminal sterilization step of the drug substance or formulation, or (b) manufacture the drug substance or products in steps where the sterile material is transferred from one sterile container to another through all the steps of manufacturing in an aseptic manner. Regardless of drug type, mode of delivery, and whether a terminal sterilization step is included, the fact remains that drug manufacturing, including drying process, is preferred to be aseptic and prevent contamination of the material.

HIGHLIGHTS

PolarDry® systems have a contained process flow with sterilizable components.

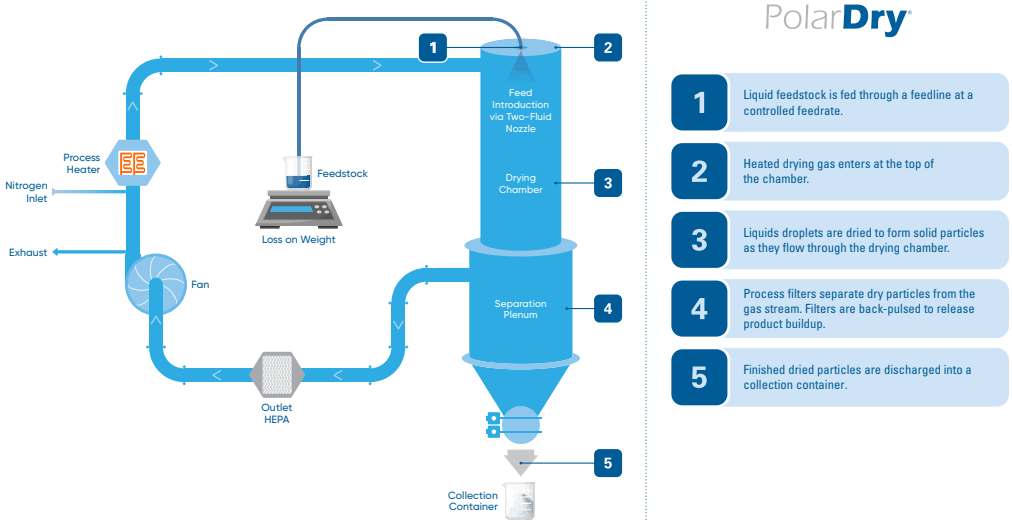
Built-in HEPA filters ensure process and atomization gases are sterile before contacting the drug product, preventing contamination.

Units operate under slight negative pressure for containment of high-potent drugs.

POLARDRY® ELECTROSTATIC DRYERS

PolarDry® electrostatic drying systems are built with contained process flows with sterilizable components to ensure an aseptic drying process, while preventing contamination and maintaining sterility. Process and atomization gas pass through HEPA filters built into the units before coming in contact with the drug substance/product. All product contact surface materials in the PolarDry® machines are made of high-quality food and pharmaceutical grade components. Fluid Air design and engineering teams work closely with customers to provide aseptic solutions specific to their needs.

Figure 1. Single pass-through schematic of a PolarDry® machine with process flow



CASE STUDY

In aseptic manufacturing and preparation, the most common potential sources of contamination include micro-organisms and cellular debris (e.g. pyrogens, endotoxins) introduced from starting materials, the working environment, and personnel. Strict microbial production controls are essential to ensure the manufacture of a drug product with consistent quality. Case studies were performed in Fluid Air pilot labs to demonstrate that the PolarDry® electrostatic drying process is an aseptic process. Established industry standards for assessing sterility and contamination were used to assess the aseptic process.

Sterility Testing

United States Pharmacopeia General Chapter 71, also known as USP <71>, is the most common method used for evaluating the sterility of pharmaceuticals. In this case study, this direct inoculation method was employed with powders obtained from the PolarDry® electrostatic drying process that were inoculated into Tryptic Soy Broth (TSB) and Fluid Thioglycollate Medium (FTM). The media tubes were visually examined for absence or presence of microbial and if no evidence of growth could be observed, then the product complied with the test for sterility.

Endotoxin Testing

The Bacterial Endotoxin Test is used to measure pyrogenic (fever-inducing) substances derived from gram-negative bacterial contamination. In this case study, an endotoxin-free formulation was processed through electrostatic drying. Powders obtained were assessed per USP <86>, LAL-based endotoxin tests. Endotoxin counts pre- and post-process were compared to assess introduction of endotoxins during processing.

PolarDry® Model 0.1

PolarDry® Model 001

RESULTS & CONCLUSION

No growth was observed in the TSB or FTM tubes inoculated with post-process collection powders. Appropriate controls were included in the testing to assess the sterility of the feedstock, media, and other reagents used in the study. Sterile process material used for endotoxin assessment was prepared from endotoxin-free excipients and the endotoxin load of the post process collection powders was compared to the endotoxin load of the feedstock. There was no increase in endotoxin seen in the collection powders.

Sterility testing per USP <71> demonstrated that product sterility is maintained during the PolarDry® electrostatic drying process. Endotoxin testing of post-process powders did not indicate an increase in endotoxin counts.

In conclusion, no microbial or endotoxin contamination is introduced during the PolarDry® electrostatic drying process.

ISO 9001:2015 CERTIFIED

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