Piramal
Pharma Solutions

LYOPHILIZATION PROCESS AT PIRAMAL

INTRODUCTION

Lyophilization is a process in which water is removed from a product after it is frozen and placed under a vacuum allowing the ice to change directly from solid to vapor without passing through a liquid phase. Typically, this dehydration process is used to preserve a perishable material and/or make the material more convenient for transport. The process usually involves three phases consisting of freezing, sublimation, and desorption.

Before a product can be lyophilized, Piramal Pharma Solutions (PPS) formulations team screens effective combinations of solvents, buffers, bulking agents, and protectants to ensure the process is successful for many different drug combinations. Generally, the drug and excipients are dissolved in water for injection (WFI) and passed through filters for sterilization. Once the team develops a successful compounding process and lyophilization cycle, the process is scaled-up for a smooth and efficient transition to larger manufacturing operations. The validation department then qualifies the lyophilization process ensuring the cycle and loading pattern allow optimal air flow. This process leads to a final product with low residual moisture, a solid and attractive cake, complete reconstitution, and resistance to physical and chemical degradation.

In production, after the compounding process, the product is filled into individual vials and partially stoppered. The vials are partially stoppered to protect the product from contamination but, due to the great amount of pressure, cannot be fully stoppered until lyophilization has occurred. Once the vials are filled and partially stoppered, they are transported to the lyophilizer using metal trays. The trays are then removed as the vials are loaded into the lyophilizer, because they could create moisture problems and block air flow.

The initial phase of the lyophilization process is the freezing procedure. Usually, the product is frozen beyond its freezing point. The lyophilizer then enters the sublimation procedure, also referred to as the primary drying phase, followed by desorption or the secondary drying phase. During this process, a vacuum is applied to the chamber and the shelves are heated in order to evaporate the water from the frozen state. The vials are then fully stoppered and removed from the lyophilizer.

The process is complicated and lengthy, but the benefits of a lyophilized product are well worth it. Aseptic handling is simplified with the ease of processing a liquid product. In a dry state, the product has enhanced stability which helps it resist degradation and transports easily. Another benefit of lyophilization is the rapid and easy dissolution of the reconstituted product. In all, PPS can provide complete lyophilization services beginning with formulation and ending with an attractive and cost-effective product.

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

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