

# Alternatives to Vial Lyophilization

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## Introduction

While lyophilization possesses many advantages, there are also drawbacks to its use. At its best, successful formulation and lyophilization yields a sterile, active, stable product that is easily reconstituted, and is sealed within its final container. However, it could not be accurately described as highly efficient, and in some cases a vial as a final container may not be optimal. For some products, reconstitution is neither fast nor easy, and sometimes a free-flowing bulk powder is more useful than a rigid cake encased in a vial.

One should always consider the liquid form as the primary alternative to lyophilization. During product development, it is standard to attempt discovery of a liquid formulation, with the lyophilized form as the main alternative. The choice of lyophilization is usually driven by the failure of liquid formulations to sustain sufficient stability over shelf life.

Examples of how some of the alternatives to lyophilization ameliorate some of the disadvantages inherent to lyophilization:

- Lyophilization has very high-energy requirements. Temperatures and pressures far from ambient must be sustained over long periods of time while supplying the energy for sublimation plus the energy for condensation. The economics and scale ability of spray-drying are such that a single spray-dryer can produce five to ten times the product that a lyophilizer of similar size and cost can produce.

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