

Lyophilisation Services

Basic Pharma can be your dedicated partner in the development and manufacturing of cGMP lyophilised (bio)pharmaceuticals. Basic Pharma offers freeze-drying (lyophilisation) solutions to preserve your valuable perishable pharmaceuticals and biologicals, thereby prolonging your product's shelf-life.



Basic Pharma Manufacturing

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Introduction

The inclusion of water influences the stability of stored pharmaceutical products. Water provides conditions that invigorates autolysis or promotes the growth of undesired organisms that have a negative impact on the stability of pharmaceuticals. The removal of water preserves perishable (bio)pharmaceuticals, resulting in extended shelf-life.

Lyophilisation is a proven technology to dry temperature-sensitive substances, resulting in dry powders. Upon rehydration, the freeze-dried product reconstitutes with the anticipated drug activity. Freeze-drying not only **increases shelf life**, it is also beneficial for cold chain storage and transportation.

Basic Pharma's **Biotechnology department** has the expertise to handle biologicals with care. Your biologicals are in good hands with us.



What Basic Pharma offers

Basic Pharma operates a **cGMP pilot freeze dryer** with a **loading capacity of 1.75 m2**. Our freeze dryer is also suitable for lyophilisation of **acetonitrile** containing compounds. Stoppering of vials is performed under **vacuum or inert gas** (Nitrogen) to prevent oxidative denaturing of your product. We are able to perform shelf loading under chilled shelf temperatures to guarantee stability of temperature sensitive products. In-process measurements include **shelf temperature** and **product temperature** (thermocouple) registration. After completion of the lyophilisation process, we can determine residual moisture content using Karl Fischer and Loss-on-Drying (LOD) tests in-house.

Our freeze-dryer is part of an **aseptic filling line** (class C cleanroom) installed in a class A isolator. This enables us to fill and lyophilise your product in a controlled environment from small to large numbers and to process **cytotoxic compounds**.

Lyophilisation capabilities

Shelve Capacity	6 shelves of 600 x 490 mm 100 mm shelf interdistance
Vial Capacity	All nested vials are suitable as long as they fit on the shelves As indication: 4,300 vials 16 mm (2R vials) per cycle 1,700 vials 22 mm (6R vials) per cycle
Shelve temperature range	-55°C to +80°C
Cleaning and sterilisation	Clean in Place using Water For Injection (WFI) Sterilise in Place using Vapourised Hydrogen Peroxide (VHP)

Basic Pharma Group

The Basic Pharma group is primarily engaged in developing, licensing, manufacturing and commercialisation of (bio)pharmaceutical products for the pharmaceutical, biotech and medical device industry.

Next to our lyophilisation services the Basic Pharma Group offers a wide range of services that are required to move your valuable project along the (bio)pharmaceutical pipeline; from initial R&D project, via clinical trials, up to commercial GMP production. We are more than happy to support you with our competences in the field of laboratory services, quality services, CMO services, IMP services, regulatory services, pharmacovigilance and clinical services.

**For additional information please contact
Basic Pharma Manufacturing.**