Services

Biopharma Technology Ltd (BTL) was formed in 1997 to offer a range of specialist services in freeze-drying. A summary of our services is given below.

Formulation Development and Analysis

BTL has worked on over 500 different formulations, from small drug molecules to large complex biomolecules. Our extensive knowledge of the freeze-drying process enables us to select excipients that are compatible with the process itself and which afford favourable thermal and mechanical characteristics to the formulation for successful processing.

Using the analytical instruments we have designed, we are able to characterise formulations in terms of thermal properties (softening events, molecular mobility) as well as specific lyophilization-related parameters such as the collapse temperature (Tc), which is the critical upper temperature limit for successful freeze-drying of almost all formulations. Our Lyostat2 freeze-drying microscope also allows determination of some of the more “qualitative” characteristics of a formulation that have traditionally been difficult to analyse, such as crust formation and crystal growth. Therefore, we are able to carry out formulation development work on a rational, scientific basis.

Freeze-Drying Cycle Development

BTL specialises in freeze-drying cycle development, which may be carried out in our own dedicated laboratory using our own freeze-dryers, or alternatively at the customer site where preferred. Following the characterisation of formulations for critical frozen state events (using Lyotherm2) and drying behaviour (using Lyostat2), together with a knowledge of factors such as container dimensions and fill volume, an initial cycle is proposed. This run is monitored and analysed, so that conditions may be refined in the next run on a rational basis. This process is repeated for each subsequent run, until suitably optimised conditions are achieved. With our extensive experience in cycle development, we typically achieve an efficient yet safe and robust freeze-drying cycle after just three runs.

Moisture Content Analysis

BTL is able to offer a moisture content analysis service for dried products. The Karl Fischer Coulometric Titration method is employed, which is a sensitive method that can be used to give precise and accurate moisture readings for small masses of material.

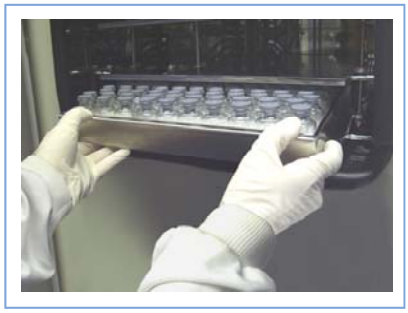
Product and Process Trouble-Shooting

BTL has consulted extensively for clients in the UK and overseas, as widely spread as Canada, Australia, Mexico, India and Scandinavia. Troubleshooting may take the form of a site visit or may be carried out remotely by phone, fax and email, depending on the nature of the problem.

Biopharma Technology Limited

Services (cont)

Pilot-Scale Freeze-Drying Runs



Using our own freeze-dryers, BTL is able to perform pilot-scale freeze-drying runs on a contract basis. The versatility of these freeze-dryers allows us to process a range of formats—vials, ampoules, bulk trays and many alternative formats—and each has a total shelf area of 0.5m^2. A PC-based control system allows coloured graphical printouts of run details for ease of interpretation and analysis.

Headspace Moisture Analysis

Frequency modulated spectroscopy (FMS) is a non-destructive technique enabling analysis of the moisture and pressure in the vial headspace. Used in conjunction with Karl Fischer analysis this technique can yield important information about the freeze-dried product and assist in fast and efficient analysis of a large number of samples. Temperature studies on headspace moisture can also be used to assess stopper moisture contribution.

Training Courses in Freeze-Drying Technology

In addition to our six-monthly training course in Winchester, UK (usually held each May and November), BTL has also gone international, running courses in Dublin, Chicago, San Francisco, San Diego, New Jersey and Amsterdam to name a few. These follow a 3-day format and cover the technical specification, engineering and design of freeze-dryers, as well as product and process-related issues, validation and troubleshooting. Anyone involved in freeze-dryer engineering or operation, formulation development or quality assurance/control will find these courses invaluable.

BTL has also completed many courses at customer sites. These have the advantage of being tailored to the customer's specific needs, as well as being a real value-for-money option for large numbers of attendees. If you are interested in a tailor-made course at your site, please feel free to contact us to discuss your requirements.

Engineering Consultancy

BTL now offers a range of Engineering Consultancy services associated with all types of machines. These services include independent analysis and assistance in:

- Design of a freeze dryer including writing the User Requirement Specification (URS)
- Attending Design Qualification (DQ) and Factory Acceptance Testing (FAT)
- Overseeing Installations and Commissioning testing
- Writing Qualification Protocols
- Executing, Overseeing or Reviewing Qualification procedures
- Provide Retrospective Qualification and Re-Qualification protocols and procedures
- Assistance in faultfinding, performance degradation, refrigerant changes etc.

Details of our products and services can also be found online at: www.lyophilizationtechnology.com.

Biopharma Technology Limited

Biopharma House, 9 Winnall Valley Road
Winchester, SO23 0LD UK
Tel: +44 1962 841092 Fax: +44 1962 841147
btl@biopharma.co.uk www.lyophilizationtechnology.com