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BTL PRODUCTS AND SERVICES

BTL 产品和服务

Biopharma Technology Limited (BTL) was founded in 1997 to offer a range of specialist services in freeze-drying. Since our foundation, we have also grown to develop, build and now market worldwide our own analytical instruments, provide regular training courses in lyophilisation technology in a number of countries and have an ever-growing list of international clients. A summary of our products and services is given below.

为业界提供系列冷冻干燥专业服务的 Biopharma Technology Limited (BTL) 成立于 1997 年。从公司创立至今，我们成功地开发，制造和销售我们自己的分析仪器。在很多国家提供冻干技术培训课程，客户不断增多。产品和服务如下。

PRODUCTS 产品

Lyostat 2 – A Fully Integrated Freeze-Drying Microscope

Lyostat 2 – 全功能冻干显微镜

Lyostat 2 is a fully integrated freeze-drying microscope that enables critical events such as collapse and melting to be observed *in situ*, as well as more qualitative characteristics such as skin or crust formation to be observed and identified. The system comprises a compound microscope, focused onto a sample that sits in a vacuum-tight, temperature-controlled stage, which acts as a 'micro-freeze-dryer'. The freezing and drying behaviour of the sample can be determined visually, and the system is controlled through a PC, which provides image- and data- capture and archiving functions.

Lyostat 2 冻干显微镜整合多种功能，可对很多关键事件进行观察。比如原位塌陷和熔化，更多的定性特征（如表面或外壳成型）的观察和确定。该系统包括一个复合显微镜，显微镜观察的对象是密封的、温度受控的“微冷冻干燥单元”内的样品。样品的冷冻和干燥过程可被可视化测定，该系统由 PC 控制，并提供了图像和数据的捕捉、储存功能。

Lyotherm 2- Electrical Impedance (Zsinφ) and DTA Apparatus

Lyotherm 2- 阻抗(Zsinφ)和 DAT (热量微分分析) 仪

Lyotherm 2 provides an integrated Differential Thermal Analyser (DTA) and *newly-developed* electrical impedance (Zsinφ) capability within one instrument. **Lyotherm 2** has been designed to measure glass transition (Tg'), eutectic (Teu) and melting (Tm) temperatures relevant to freeze-drying formulations. The measurement of (Zsinφ) can give important information as to the behaviour of the frozen solute phase.

Lyotherm 2 在一台机器中整合了热量微分分析仪和最新开发的阻抗(Zsinφ)性能。**Lyotherm 2** 可测量与冻干配方有关的玻璃态转化温度(Tg')、共熔温度(Teu)、融化温度(Tm)。对(Zsinφ)的测量可为冻干溶解阶段提供重要的信息。



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Lyostat 2 and **Lyotherm 2** together provide valuable information that can be fed back into both formulation and cycle development processes. In addition, BTL has more innovative analytical instruments in the development pipeline.

Lyostat 2 和 **Lyotherm 2** 共同提供很有价值的信息，这些信息可以用于产品配方和过程开发。另外，BTL 还有更多的用于开发的创新性分析仪器。

SERVICES 服务

Formulation Development and Analysis 配方开发和分析

BTL has carried out formulation development for a wide range of products, 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.

BTL 完成了众多的产品（从很小的药物分子到大而复杂的生物分子）的配方开发。得益于我们对冻干过程的广泛知识，使我们可以选择既利于冻干过程又具备良好热效能和生产特性的赋形剂，从而确保成功的冻干过程。

Using the analytical instruments we have designed and now market worldwide, we are able to characterise formulations in terms of thermal properties (glass transitions, molecular mobility) as well as specific lyophilisation-related parameters such as the collapse temperature (T_c), which is the critical upper temperature limit for successful freeze-drying of almost all formulations. Our **Lyostat 2** freeze-drying microscope also allows determination of some of the more 'qualitative' characteristics of a formulation that have traditionally been difficult to analyse. Therefore, we are able to carry out formulation development work on a rational, scientific basis.

利用我们设计的、并被国际市场广泛认可的分析仪器，我们可以按照热性质（玻璃态转化温度、分子活性）和特殊的冻干相关参数，如塌陷温度 T_c （该温度是几乎所有冻干配方的上限临界温度）对冻干配方进行定性和区分。我们的 **Lyostat 2** 冻干显微镜，可以观察、确定更多的、传统分析方法所不能完成的冻干配方的特征定性。因此，我们的冻干配方开发建立在合理和科学的基础上的。

Freeze-Drying Cycle Development 冻干周期开发

BTL also specialises in freeze-drying cycle development, which may be carried out at the BTL laboratory using our VirTis Genesis freeze-dryer, or alternatively at the customer site where preferred. Following the characterisation of formulations for critical temperature and drying behaviour, together with a knowledge of factors such as container dimensions and fill volume, an initial cycle is proposed based on these parameters. 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.



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BTL 也专长于研究冻干周期过程，可使用我们的 VirTis Genesis 冻干机在 BTL 实验室或客户处完成实验。通过对临界温度、干燥过程及其他因素（如容器直径、灌装量）等配方参数的定性和测量，我们可以提出初级的冻干周期建议。通过对运行过程的监视和分析，基于合理的分析可以在下一次运行时对参数进行优化。不断重复该过程，直至达到最佳的运行条件。

Pilot-Scale Freeze-Drying Runs 中试冻干运行

Using its two VirTis Genesis 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 machine has a total shelf area of 0.5m². A PC-based control system allows colour graphical printout of run details for ease of interpretation and analysis.

使用两台 VirTis Genesis 冻干机，BTL 可以代工方式为客户进行多批次冻干中试。此冻干机多功能性可用于多种容器—安瓿、西林瓶、大盘及其他多种形式，每台设备的冷冻干燥（shelf area）面积为 0.5m²。计算机控制的控制系统，可实现运行细节的彩色图形打印，便于理解和分析。

Moisture Content Analysis 水分含量分析

BTL is also 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.

BTL 可提供冻干产品的水分含量分析服务。采用 Karl Fischer Coulometric 滴定法，该方法灵敏度高，测量水分含量精确可靠。

Product and Process Troubleshooting 解决产品和工艺问题

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

BTL 曾广泛地为英国和海外客户提供咨询服务，如澳大利亚，墨西哥和北欧的客户。取决于问题的类型，解决技术问题可通过走访现场，电话，传真和电子邮件进行。

Training Courses in Freeze-Drying Technology 冻干技术培训课程

In addition to running our annual training course in Winchester, UK (held each Autumn), BTL has also completed many courses at customer sites, which have the advantage of being tailored to the customer's specific needs. If you are interested in a tailor-made course at your site, please feel free to contact us to discuss your requirement in further detail.

除了每年秋天在英国 WINCHESTER 举行的年度培训外，BTL 还经常在现场进行培训，这样可更按客户的特殊需求进行。如您对在现场进行培训感兴趣，请与我们联系。



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We have also gone International, running courses in Dublin, Chicago, San Francisco, San Diego and Amsterdam, with further courses being planned in Europe and the USA at regular intervals. These follow a 3-day format and will 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.

我们经常在国外进行这类讲座，如在都柏林，芝加哥，三藩市，圣地亚哥和阿姆斯特丹等。此讲座一般为期三天，包含技术规格，冻干机的工程设计，以及产品和工艺过程相关问题，验证和故障排除等。那些与冻干工程，操作，配方开发或质量保障/控制有关的人士将发现这些讲座时非常有益和无价的。

Further details of BTL's Products and Services may be found on our website at:

关于 BTL 产品和服务的详情请访问我们的网站：

www.lyophilizationtechnology.com