



ANALYTICAL INSTRUMENTS

IN-DEPTH FREEZE DRYING
CHARACTERISATION



WWW.BIOPHARMA.CO.UK

OVERVIEW

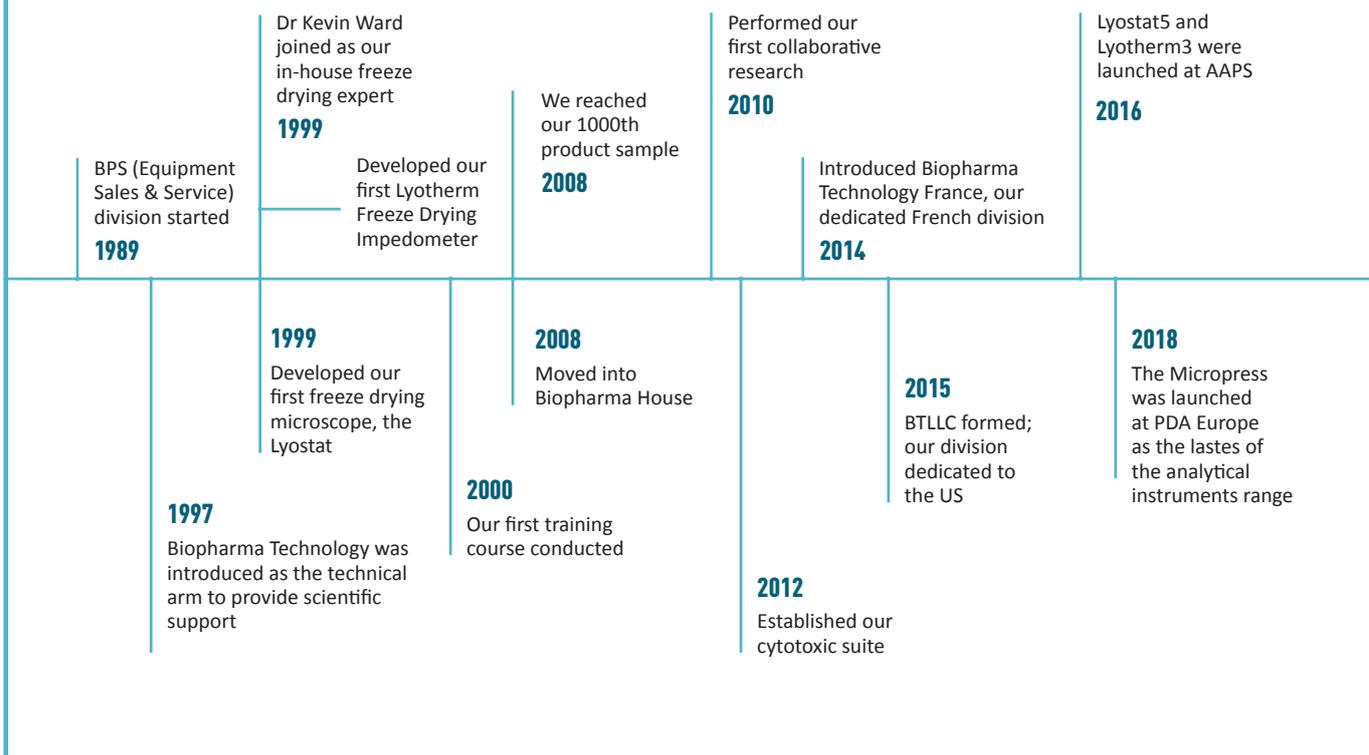
In 1997 Biopharma Group established an in-house R&D consultancy and lab analysis division to provide unbiased contract research, analysis & development services, training and analytical instrumentation internationally.

We offer uniquely comprehensive services & training courses (scheduled or customised) covering all aspects of freeze drying technology from pre-formulation through to production & dried product analysis and remains at the forefront of analytical instrumentation development, having launched the Lyostat5, Lyotherm3 and most recently – MicroPress.

OUR MISSION & PHILOSOPHY

Biopharma Group is dedicated to providing its clients with the highest possible standard of service, support and products. Our mission is to meet the precise needs of our customers' projects appropriate to the size and stage of the project.

Biopharma's philosophy is to augment its customers in-house expertise and work together to make each project a success.



ANALYTICAL INSTRUMENTS

A rational, knowledge-based approach to designing and developing successful freeze drying formulations and cycles requires information about how the product responds to different processing conditions.

Our analytical instruments have been designed to provide the most advanced data on critical events in freeze drying projects to inform decision making and product characterisation stages of the project. In addition, Biopharma Group's analytical instruments have been engineered with the end users in mind, solving many technical and ergonomic issues faced by those conducting freeze drying product development.

OUR RANGE OF PRODUCTS

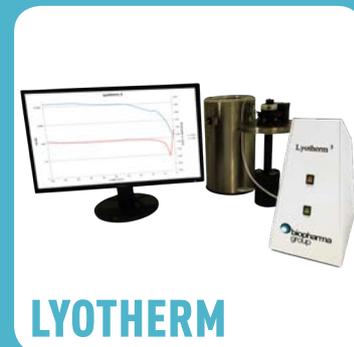
Biopharma has developed three advanced analytical instruments – Lyostat freeze-drying microscope, Lyotherm frozen stage analyser and MicroPress which qualifies lyo-cake robustness. We also offer the DSC Stage – an optional add-on expanding the Lyostat and Lyotherm capabilities.



LYOSTAT



OPTICAL DSC



LYOTHERM



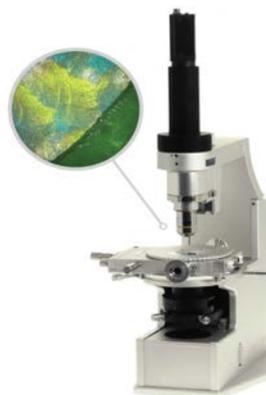
MICROPRESS

FREEZE DRYING PROCESS

PROOF OF CONCEPT	DEVELOPMENT	POST PROCESS
LYOSTAT	LYOSTAT	OPTICAL DSC
LYOTHERM	LYOTHERM	MICROPRESS
OPTICAL DSC	OPTICAL DSC	

LYOSTAT5

FREEZE DRYING MICROSCOPE



- **Achieve a safe, robust and cost efficient cycle development:** identify collapse/eutectic temperatures, crystallisation phenomena, potential for skin/crust formation, and the effects of annealing on ice crystal growth and solute structure
- **Real-time digital video and measurement:** using a high performance digital USB camera to determine the exact point of collapse, capture up to 80 GB of information
- **Optimised Optical System:** fewer lenses than compound microscopes for clearer images, LED lamp with an efficient custom-designed electronics module and lifetime of more than 60,000 hours
- **Motorised vacuum control:** chamber pressure displayed in mBar, kPa or mTorr enables close investigation of the effects of pressure on sample collapse
- **Liquid Nitrogen Cooling System:** automatic twin-pump cooling system including 2L Dewar and flexible insulated tubing, twin pumps for faster cooling
- **User-friendly software:** full control over temperature programmer active ramp information and stage pressure, create temperature profile of several ramping and holding steps in a simple on-screen data table

OPTICAL DSC

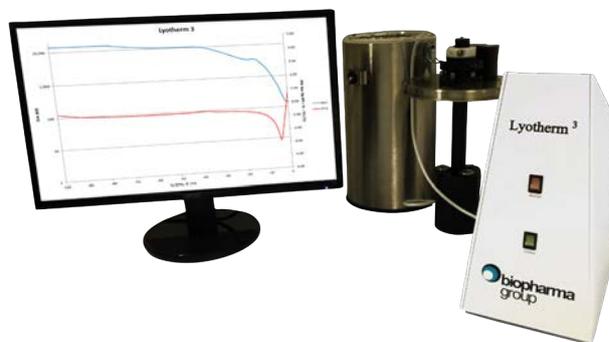
CORRELATE DSC ANALYSIS WITH IMAGING



- **Conduct closed experiments:** the Optical DSC (Stage) system is ideal for measuring glass transitions, crystallisation and melting events
- **Optical Capabilities:** the stage has been optimised to allow simultaneous imaging and DSC analysis; fitted with a quartz window for high quality image capture and recording
- **Thermal Analysis by Structural Characterisation (TASC):** an optional module that tracks changes in surface structure and is highly sensitive to glass and melt transitions. In addition to the DSC signal, TASC enables to analyse different parts of the same sample to identify inhomogeneities
- **Highly Sensitive:** study thermal transitions at low heating rates, or with small sample sizes, with no loss of sensitivity
- **Wide Temperature Range:** temperature control range from -180°C to $+450^{\circ}\text{C}$, for a wide variety of experiments and applications. The standard 2L liquid nitrogen dewar provides cooling for several hours
- **Modular System:** Optimal DSC stage is designed to be compatible with the Lyostat5, sharing the same software, optical system and liquid

LYOTHERM3

FROZEN STATE ANALYSER



- **Add a new dimension to the data of this critical stage:** the Lyotherm3 combines electrical and thermal techniques, enabling you to do two analyses at the same time:
- **Impedance Analysis ($Z\sin\phi$):** is a fixed frequency dielectric analysis providing an indication of molecular mobility, including events not picked up by thermal methods like DTA or DSC
- **Differential Thermal Analysis (DTA):** measures the difference in temperature between a sample and a reference, highlighting exothermic and endothermic events e.g. crystallisation, eutectic melting and glass transitions
- **Most accurate analysis data available on the market:** the Lyotherm3 simplified operation to increase reliability of results providing you with clear graph data and flexibility during post-analysis
- **Optimised for frozen state analysis:** identifies viscosity changes and critical parameters of samples such as T_g' , crystal transitions, T_{eu} and softenings within the frozen structure
- **Great control and optimization:** alarms and liquid nitrogen precision allow greater control over analysis, while the updated control unit and wiring design reduce the benchtop footprint

MICROPRESS

QUANTIFYING LYO CAKE ROBUSTNESS



- **Determine key parameters for cake quality:** MicroPress uses a linear actuator to gently compress the cake to determine the stiffness (Young's Modulus) and strength (max stress at failure) of lyophilised cakes
- **Easily measure physical properties:** identify vials with collapse, microcollapse & crust formation
- **Quick analysis time:** as standard, less than 1 minute, in situ analysis – no sample prep required, quickly compare multiple vials
- **Integrated software:** the resulting stress-strain profile captured during analysis is then exportable to Microsoft Excel for further interpretation
- **Ensure product quality to the point of delivery:** determine how the cake will behave during handling and shipment

KEY BENEFITS OF USING BIOPHARMA



INSTALLATION & TRAINING

Installation and training packages are available for new and existing systems. The two-day service includes testing the equipment to ensure it is performing to specifications and explanation and demonstration of use. Unlike other suppliers, all our installation and training is carried out by scientists with practical, first-hand experience of the systems and interpretation of data.



MAINTENANCE & REQUALIFICATION

In order to ensure continued smooth and precise operation of your instruments we recommend that maintenance is carried out every year. Re-qualification can also be carried out to provide evidence of the accuracy of the data. Re-training is especially recommended when purchasing an upgrade or new accessories.



R&D CONSULTANCY AND ANALYTICAL LAB SERVICES EXPERTISE

Biopharma Group's R&D consultancy and lab services division has over twenty years' experience in freeze drying research and development. Our expertise includes characterisation services, formulation development, cycle development and post process analysis. We have developed efficient and robust cycles for a wide variety of products including foods, small molecules, diagnostic reagents and biological materials such as bacteria, viruses and blood products.



TRAINING COURSES

Biopharma runs scheduled and customised training courses on freeze drying technology and applications with highly experienced lecturers, during which we demonstrate how to use our machines*.

*Winchester Training Courses

TECHNICAL DATA

LYOSTAT5

- Temperature range -196°C to +125°C
- 100 Ohm platinum resistor sensor for temperature monitoring & control (DIN Class A to 0.1°C)
- Sample chamber vacuum tight to 10⁻³ mbar
- High-resolution, 2.3 megapixel sensor
- Capture up to 80GB information
- Oerlikon Leybold D2.5E rotary vane vacuum pump with pumping speeds of 3.2m³/h

LYOTHERM3

- Temperature range -196°C to +60°C
- 2 Pt 100 temperature probes with accuracy of ±0.3°C at 0°C
- Sample volumes from 2ml - 4ml
- Impedance probe operating between 1Ω -14MΩ at 1,000Hz
- Double insulated liquid nitrogen Dewar
- 220/240V 50Hz or 120V 60Hz variable power supply
- Small bench-top footprint (500mm x 400mm)

OPTIONAL DSC

- Temperature range -180°C to +450°C
- 2L LN Dewar
- Heating rate of 0.1°C to 30°C per minute
- <0.1°C temperature stability
- Aluminium and Sapphire sample pans
- Option of Silver or Sapphire furnace lid
- 0.01mW accuracy
- 8.2mm objective working lens distance

MICROPRESS

- Operating temperature -10°C to +40°C
- Speed: 0.0012 10mm/s
- Force: 0.1-5 N
- Accuracy: ± 0.03%
- Up to 25 samples per group
- Calibrates to any size vial
- Custom indenters available
- Analysis time: 30-90 seconds
- 9 customisable parameters

ANALYSIS PROVIDED

		EVENT/INSTRUMENT	OPTICAL DSC	LYOSTAT5	LYOTHERM3
FROZEN STAGE	Micro Collapse	✗	✓	✗	✗
	Collapse	✗	✓	✗	✗
	Glass Transition (T _g ')	✓	✗	✓	✓
	Crystallisation	✓	✗	✓	✓
	Eutectic melt	✓	✓	✓	✓
		EVENT/INSTRUMENT	MICROPRESS	OPTICAL DSC	
DRY STAGE	Mechanical properties	✓	✗		
	Cake strenght (σ)	✓	✗		
	Glass Transition (T _g)	✗	✓		

VISIT OUR WEBSITE:

www.biopharma.co.uk

TEL +44 (0)1962 841092 or 0845 189 6016

FAX +44 (0)1962 841147

EMAIL btl@biopharma.co.uk

OUR OFFICE HOURS:

08:30-17:00 Monday to Thursday

08:30-14:30 Fridays

Biopharma House
Winnall Valley Road
Winchester
Hampshire
SO23 0LD

