ANALYTICAL INSTRUMENTS

IN-DEPTH FREEZE DRYING CHARACTERISATION

biopharma group

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ANALYTICAL INSTRUMENTS

What?	When?	Why?
Lyostat		
Collapse Annealing	Max Temp for FD Annealing is benefit?	Efficient Process High yield Homogenous batch

Lyotherm		
Thermal treatment Glass Transition Softening	Freezing steps required Max Temp for FD Mobility changes	Efficient process Homogenous batch Protection against defects

MicroPress		
Mechanical structure	Mimic shipping conditions Show batch consistency	Ensures strong product Ensures batch consistency

TECHNICAL DATA

LYOSTAT5

- Temperature range –196°C to +125°C
- Sample chamber vacuum tight to 10^{-3} mbar
- High-resolution, 3.2 megapixel sensor
- Capture up to 80GB information
- Rotary vane vacuum pump

OPTIONAL DSC

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

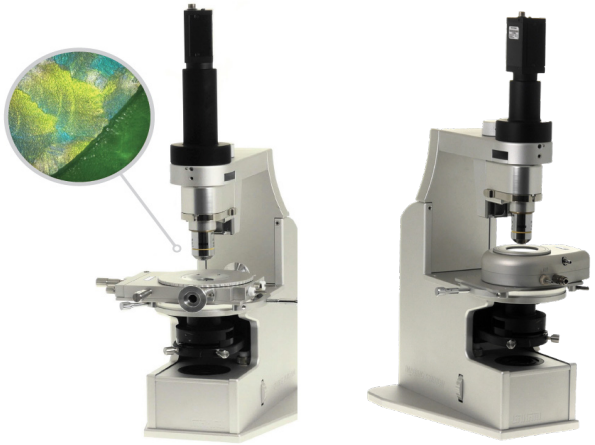
LYOTHERM3

- 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
- Small bench-top footprint (500mm x 400mm)

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

LYOSTAT5
FREEZE DRYING MICROSCOPE

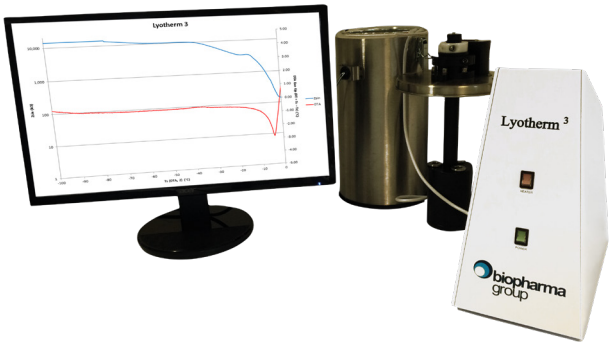


- **Achieve a safe, robust and cost efficient cycle development:** identify collapse/eutectic temperatures, crystallisation phenomena, potential for skin/crust formation, and the effects of annealing on ice crystal growth and solute structure.
- **Real-time digital video and measurement:** using a high 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°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 (ZSinϕ):** 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
MECHANICAL PROPERTY ANALYSER

- **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 and lyobeads.
- **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 GROUP

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

COMPANY PROFILE

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.

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