



*Freeze drying and sterilisation
processes R&D Laboratory*

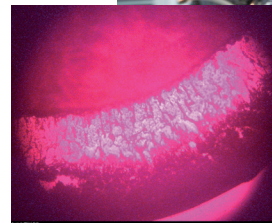


Telstar makes its Process Laboratory available to you ...

Current manufacturing regulations require medicines to be qualified and prepared following GMP (Good Manufacturing Practice) and to the standards defined by the regulatory authorities. Accordingly, there must be Standardised Operating Procedures to enable determination and reproduction of the characteristics and preparation stages of a particular pharmaceutical form.



Samples of product to be sterilized



Cryogenic microscope for determination of the collapse temperature.

...freeze drying and sterilisation expertise.

Telstar makes available to its clients a team of technicians and specialists who offer a complete consultancy service for the development, qualification and validation of the cycles required for product freeze drying and sterilisation.

Freeze drying: An in-depth study of product thermal characteristics, freezing and drying steps can result in a significant improvement in product quality and productivity.

Sterilization: Optimization of process conditions will enable container (vial, ampoule, bottle, bag, etc.) integrity to be maintained and result in shorter cycles with lower cost.



Development of freeze drying recipes

Expert users may also make use of Telstar's services to optimise elderly recipes which were designed at a time before present-day analytical methods became available.

A preliminary study of the thermal characteristics of the product makes it possible to adjust the working conditions of the freeze dryer in order to increase the sublimation rate without compromising the final quality of the product. This may result in a considerable saving in the cycle time, with a consequent increase in productivity.

Validation of new installations will also enable minor changes in the freeze drying process to be carried out and validated at low cost.

Telstar has a specialised laboratory in which the most appropriate recipes are studied and developed: the necessary tests are carried out to ascertain the characteristics of products before they are freeze dried; the parameters of the freeze drying cycle are established; the necessary product batches are freeze dried to optimise the recipe, and; final quality control tests are carried out.

Telstar Process Laboratory Services can provide valuable advice to new users of freeze drying by offering specific freeze drying courses, adaptation of recipes to new installations and obtaining real samples for preliminary study.

Analysis of the product before and after freeze drying

Analytical study to determine the necessary parameters relating to the product freezing phase. Determination of the product's thermal characteristics:

- Incipient melting temperature.
- T_e Eutectic temperature of the solution.
- T_g Glass Transition Temperature determined by DSC (Differential Scanning Calorimetry).
- T_c Collapse temperature, observed in the cryogenic microscope.

These tests are used to identify the critical temperature for the product so that a safe temperature can be established for use during freeze drying. It is also possible to evaluate the potential benefits of heat treatment or annealing during the product freezing process.

- Residual moisture measurement (%HR).
- Confirmation of vacuum in sealed containers: Final high frequency, non-destructive vacuum test.





Design and optimisation of the freeze drying recipe and obtaining of test batches

The preliminary analyses of the product enables definition of the freeze drying recipe with confidence. Optimisation of this initial recipe will be achieved by successive tests in which defects such as collapse, excessive cycle duration, turbidity, excessive reconstitution time, excessive residual moisture, and breakage of vials will be corrected or improved.

Development of sterilisation cycles

The Laboratory has a specialised autoclave which enables sterilisation of samples by the following methods:

Pure dry steam sterilisation



Autoclave Telstar Steridelta A

Air counter-pressure steam sterilisation



Autoclave Telstar Steridelta W

Water counter-pressure sterilisation

Sterilisation of Client product in the laboratory's autoclave

Tests in the autoclave can determine the optimum conditions for sterilisation for all types of product: solid, porous, liquid, plastic, and so on.

Product formats which usually require an in-depth study are plastic containers with liquid inside. The overpressure exerted by the gas inside the container during sterilisation may permanently deform it so as to render it unusable.

The external counter-pressure which needs to be exerted throughout the process to prevent deformation of the container is determined in the laboratory autoclave. This counter-pressure may be exerted with the steam-air mixture or with superheated water. The choice of which system is most appropriate will depend upon the state in which the container is to emerge from the autoclave: dry or wet.

The small volume of the autoclave chamber makes it possible to carry out tests with small quantities of containers. The results can then be easily transferred to an industrial scale plant.



Specialised training

- 2 – 3 day training courses for maintenance and production staff, with LYOBETA type pilot freeze drying equipment for monitoring complete processes and creating recipes, plus training on industrial equipment.
- Specific courses on particular topics: programming, qualification, refrigeration, creation of recipes, optimisation of freeze drying cycles, and; special operations such as: control of the process by resistivity, in-process testing with a moisture control probe, barometric process control (BTM).

Equipment and systems available in the Telstar Laboratory

- Lyoquest model laboratory freeze dryer
- LYOBETA-25 model pilot freeze dryers. Equipped with:
 - PLC-based control and SCADA (supervisory control and data acquisition) system
 - Isolation valve between chamber and condenser
 - Stoppering device
 - Measurement of the sublimation front temperature, flow rate and other parameters by DPE (Dynamic Parameters Estimator)
 - Vacuum control by microbleed modulating valve
 - Vacuum reading in parallel with Baratron vacuum capacitance manometer and Pirani gauge
 - Moisture sensor in the chamber
 - Measurement of the temperature of the product with PT100 probes and thermocouples
 - Sample thief device
- Cryogenic microscope
- System for the rotary freezing of bottles in an alcohol bath
- Resistivity control equipment
- Vial filling equipment
- Final moisture control by the Arizona Instruments Computrac method.
- High frequency system for vacuum control in sealed bottles (non-destructive test)
- Laminar flow cabinet for handling powder products. Preparation of solutions for freeze drying
- Sterilisation autoclave using pure dry steam, steam-water counter-pressure and superheated water.



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