Development of sterilisation cycles

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

- Development of sterilisation cycles
- Results can then be easily transferred to an industrial scale plant.
- The small volume of the autoclave chamber makes it possible to carry out tests with small quantities of containers.
- Containers are to emerge from the autoclave: dry or wet.
- The choice of which system is most appropriate will depend upon the state in which the container is determined in the laboratory autoclave. This counter-pressure may be exerted with the steam-air mixture.
- The external counter-pressure which needs to be exerted throughout the process to prevent deformation of the inside the container during sterilisation may permanently deform it; special operations such as control of the process by sensitivity, improvements testing with a maximum control probe, barometric process control (BTM).

Specialised training

- ISO 9001: Certified Company.
- Products formats which usually require an in-depth study are plastic and so on.
- Specific courses on particular topics: programming, qualification, optimisation of freeze drying cycles, and special operations such as control of the process by sensitivity, improvements testing with a maximum control probe, barometric process control (BTM).

Equipment and systems available in the Telstar Laboratory

- Lyopholizer model laboratory freeze dryer
- LYOBETA-25 model pilot freeze dryer. Equipped with:
  - PLC/Touch panel and NcA (automatic control and data acquisition) system
  - Analyses valve between chamber and condenser
  - Stepping device
  - Measurement of the sublimation front temperature, flow rate and other parameters
- Vaporisation control by microliter modulating valve
- Vacuum monitoring by Pirani vacuum capacitance manometer and Pirani gauge
- Vacuum control by microbleed modulating valve by DPE (Dynamic Parameters Estimator)
- Measurement of the sublimation front temperature, flow rate and other parameters
- Stoppering device
- Isolation valve between chamber and condenser
- PLC-based control and SCADA (supervisory control and data acquisition) system.
- 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 sensitivity, improvements testing with a maximum control probe, barometric process control (BTM).
- 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.

Sterilisation of Client product in the laboratory’s autoclave

- 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.
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.

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.

Telstar makes its Process Laboratory available to you ...

...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

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

- Incipient melting temperature.
- Tg Glass Transition Temperature determined by DSC (Differential Scanning Calorimetry).
- Tc Collapse temperature, observed in the cryogenic microscope.
- Residual moisture measurement (%HR).
- Confirmation of vacuum in sealed containers: Final high frequency, non-destructive vacuum test.

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.

Analytic study of the product before and after freeze drying

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

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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:

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

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

The preliminary analyses of the product enable definition of the freeze-drying recipe with confidence. Optimization 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.

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

- Development of sterilisation cycles
- Pure dry steam sterilisation
- Water counter-pressure steam sterilisation
- Air counter-pressure steam sterilisation

**Specialised training**

- **Client training** course for maintenance and production staff, with an ISO9001 type pilot freeze drying equipment for monitoring complete processes and creating recipes, plus training on industrial equipment
- Specific training on particular topics: programming, qualification, validation, number of recipes, optimisation of freeze drying cycles, and specific operations such as control of the process by moisture, improvements testing with a maximum control probe, parameters process control (BTP).

**Equipment and systems available in the Telstar Laboratory**

- Lyophilised model/laboratory freeze dryer
- LYOBETA model pilot freeze dryer, equipped with:
  - PLC control and SCADA supervision control and data acquisition system
  - Analytical valve between chamber and condenser
  - Stepping device
  - Measurement of the sublimation front temperature, flow rate and other parameters
  - DPI (Dynamic Parameters Estimator)
  - Vacuum control by microcontroller
  - Vacuum monitoring with a Pirani vacuum capacitance manometer and Pirani gauge
  - Temperature sensor inside the chamber
  - Measurement of the temperature of the product with PT100 probes and thermocouples
  - Sample thief device
  - Cryogenic microscope
  - System for the rotary feeding of bottles in an alcohol bath
  - Electrical control equipment
  - Void filling equipment
  - Void vacuum control by the Arizona Instruments Computrac method
  - High frequency system for vacuum control in sealed bottle (non-invasive test)
  - Universal flow calibrator for handling powder products. Preparation of solutions for freeze drying
  - Sterilisation in a autoclave using pure dry steam, steam-water counter-pressure and superheated water

**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 indepth study are plastic containers with liquid inside. The asepsis achieved by the process 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.
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- Development of sterilisation cycles
- Pure dry steam sterilisation
- Air counter-pressure steam sterilisation
- Water counter-pressure sterilisation

Sterilisation cycles can then be easily transferred to an industrial scale plant.

The Laboratory’s autoclave enables the following types of sterilisation:

- Pure dry steam sterilisation
- Steam-water counter-pressure sterilisation
- Air counter-pressure steam sterilisation
- Laminar flow cabinet for handling powder products. Preparation of solutions for sterilisation
- High frequency system for vacuum control in sealed bottles (non-destructive test)
- Final moisture control by the Arizona Instruments Computrac method.
- Vial filling equipment
- Resistivity control equipment
- Cryogenic microscope
- LYOBETA-25 model pilot freeze dryers. Equipped with:
  - Lyoquest model laboratory freeze dryer
  - Resistivity control and SCADA (supervisory control and data acquisition) system
  - Air counter-pressure steam sterilisation
  - Isolation valve between chamber and condenser
  - Thermocouples
  - Measurement of the temperature of the product with PT100 probes and Pirani gauge
  - Vacuum control by microbleed modulating valve
  - Vacuum reading in parallel with Baratron vacuum capacitance manometer and DPE (Dynamic Parameters Estimator)
  - Measurement of the sublimation front temperature, flow rate and other parameters
  - Sample thief device
  - Specific courses on particular topics: programming, qualification, refrigeration, creation of recipes, optimisation of freeze drying cycles, plus training on industrial equipment.

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, improve testing with a vacuum control probe, barometric process control (BTM).

Equipment and systems available in the Telstar Laboratory

- Freeze drying and sterilisation processes R&D Laboratory
- ISO 9001: Certified Company
- Telstar reserves the right to improvements and specifications changes without notice.