

SMALL-SCALE STERILE FACILITY



GlaxoSmithKline

Overview

The Parma Small-Scale Sterile Facility provides flexible services for the formulation and filling of **sterile liquids** and **freeze-dried** products for development and clinical supply purposes.

Able to handle products in 3ml, 10ml, 17ml and 30ml vials, this flexible facility has a total capacity of from 40 to 60 batches per year and was authorised as a GMP plant by the Italian Authorities (AIFA) in June 2008.

Equipment

- *Compounding* in mobile glass/stainless steel vessel (1L to 150L) or Disposable mixing bag (10L to 200L)
- Aseptic disposable in-line filtration routinely used
- *Filling and Crimping* from 0.5 ml to 30 ml at 40-60 pcs/min
- *Freeze-drying*: 3,4 sqm Lyo, equipped with liquid nitrogen technology. The lyo max capacity ranges from 5,000 vials (10 ml and 17 ml) to 10,000 vials (3 ml) per batch

Supporting Technologies

- Dispensing under isolator technology
- CIP/SIP station for stainless steel compounding vessel (Cleaning In Place/Sterilisation In Place)
- Autoclaving for sterilisation cycles
- Disposable or stainless steel filling kit available
- Sterile materials (e.g. stoppers and over-seals) loaded through alpha/beta port
- Automated Cleaning In Place/Sterilisation In Place, Integrity Test and Leak Test on freeze dryer
- Supervisory Control And Data Acquisition System (SCADA) for production activities



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