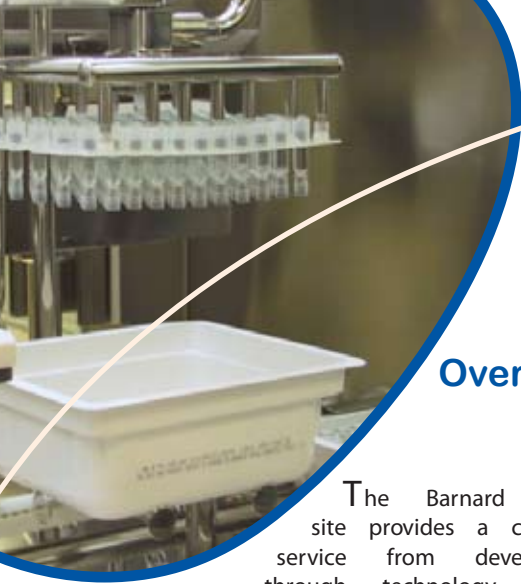


Steriles Production Facility

Barnard Castle, United Kingdom
New Product and Global Supply Site





Overview Equipment

The Barnard Castle site provides a complete service from development through technology transfer, artwork and pack development, filling, inspection, labelling and packaging to shipping.

The Steriles production facility is a state of the art plant for development, clinical and commercial sterile manufacture of liquid fill syringe and vial products.

The manufacturing process extends from formulation to sterilising filtration, filling, sealing and terminal sterilisation (if required).

An inspection stage comprising of leak testing or automatic crack detection and automatic cosmetic inspection completes these manufacturing operations.

The packaging process ranges from bulk packaging to labelling and finished packaging including syringe devices for subcutaneous dosing.

The facility is approved by and supplies products to over 100 global markets including USA, Canada, EU, International and Japan.

The facility is a multi-product plant capable of producing biopharmaceutical products, conventional small molecule liquid pharma products and sterile emulsion products in vials from 0.5ml to 100ml and syringes from 0.1ml to 20ml.



- Manufacturing in fixed or mobile stainless steel vessels (5l to 1000l) or disposable mixing bags (20l to 500l)
- Filling in vials from 0.5ml to 100ml with in process control fill weight testing on two Restricted Access Barrier (RAB) technology filling lines.
- Aseptic filling in syringes from 0.1ml to 10ml with automatic in process control fill weight testing on an Isolator filling line complete with low shear filling systems (time pressure and peristaltic pumps).
- Filling in syringes, on a second RAB filling line, from 0.5ml to 20ml with automatic in process control fill weight testing.
- Automatic inspection for leaks / crack detection and particulates for vials and syringes. Manual inspection can be performed for those products which are technically unable to be automatically inspected.
- Fully automatic packaging lines for vials, syringes and bespoke devices. Manual packaging can be performed for those packs which are technically unable to be automatically packed or have very low demand.
- Freezer and Coldstore capacity for drug substance and drug product storage.

Key Characteristics / Technologies

- Isolator technology for dispensing
- Controlled thaw technology for frozen bulk drug substance
- Disposable or stainless steel manufacturing and filling equipment available.
- Homogeniser technology for production of emulsion products
- Isolator and Advanced restricted access barrier (RAB) filling lines
- Automation managed by Supervisory Control and Data Acquisition (SCADA)
- Clean in place / Sterilise in place (CIP/SIP) systems integrated to give optimum automated cleaning and sterilisation of liquid path to point of fill.
- Automated Vapourised Hydrogen Peroxide (VHP) cycle for isolator sanitisation
- Grade A continuity from autoclave to filling machine.
- Automatic continuous particle and microbiological monitoring systems in classified areas
- Autoclaving for terminal sterilisation of products (where required)
- Automated leak detection, crack detection and cosmetic/particulate inspection.
- Cold / frozen supply chain and logistics expertise
- Technical expertise and proven capabilities to manage the development, launch and supply of new, in-licensed or transferring products to global markets including products utilising devices.

