



ROMFORD

# Terminally Sterilised Ampoules:



Headcount:

**404**



Authorizations:



FDA U.S. FOOD & DRUG ADMINISTRATION

USA

MHRA  
Regulating Medicines and Medical Devices

UK



SAUDI ARABIA



KOREA



KENYA

## Product Forms:

Terminally sterilised ampoules, aseptic and Terminally Sterilised PreFilled Syringes, Oral Liquids



Number of units produced: **1.3** Million  
**50** Million

## Strong expertise



Handling controlled drugs, Sterile processes

## Equipment:

- 4 ampoule filling machines (1ml to 20ml)
- 3 automatic inspection machines
- High Speed ampoule packing
- Oral Liquid Filling and Packing
- Aseptic PFS Filling (1.3m)
- Autoclaves and Dry Heat Oven





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# Terminally Sterilised Ampoules:

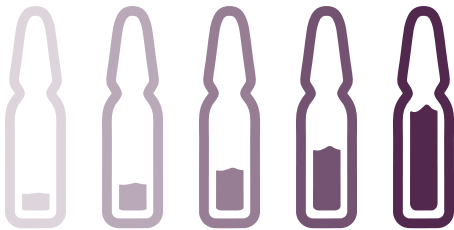
## CAPACITY:

**75 million** ampoules per year



## SIZES:

We make the following ampoule sizes



1ml 2ml 5ml 10ml 20ml

We also fill and terminally sterilise small bottles (less than 10ml) with stoppers and caps.

## EQUIPMENT:



### Manufacturing

- Stainless steel manufacturing vessels ranging from 5 litres to 1,000 litres and have the ability to manufacture any batch size within this range
- Nitrogen purging throughout the manufacture and filling process.



### Filling

- 4 filling machines, with a maximum speed of 400 ampoules per minute
- The table below gives more detail of the machine speeds.

MACHINE	1ml	2ml	5ml	10ml	20ml	bottles
8 header	400	400	N/A	250	N/A	N/A
Combination bottle and ampoule filler	200	200	166	133	91	60
4 header	200	200	N/A	N/A	N/A	N/A
Single Header	50	50	40	30	20	N/A





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# Terminally Sterilised Ampoules:

 Ethypharm



## Sterilisation

- 2 Fedegari autoclaves for sterilisation of aqueous solutions
- 1 dry heat oven for sterilisation of oil based products.



## Inspection

- We inspect ampoules via semi-automatic inspection or fully automated inspection
- 3 x Seidenader semi automatic inspection machines
- 3 x Brevetti fully automatic inspection machines with a maximum speed of 300 ampoules per minute
- Automatic inspection machine also performs high voltage leak detection
- Pressure decay leak detection is also available for products that are not compatible for high voltage testing.



## Labelling

- 3 x B+S labellers with a maximum speed of 300 ampoules per minute.



## Packing

- 1 high speed Marchesini packing line for large batch sizes
  - 960 ampoules per minute for 1ml and 2ml ampoules
  - 600 ampoules per minute for 5ml and 10ml ampoules
- 1 lower speed line for small batch sizes
  - 200 ampoules per minute for 1 and 2ml ampoules
- Hand packing available for 20ml ampoules
- Serialisation is available.





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# Pre-Filled Syringes:

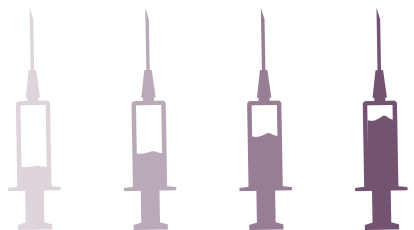
## CAPACITY:

**2.5 million** syringes per year 

Demand for our products is **1.4 million** per year

## SIZES:

Ability to fill the following syringe sizes:



**1ml**  
with  
staked  
needle

**2ml**

**5ml**

**10ml**



## Equipment

- Grade C manufacturing facility
  - Stainless steel vessels up to 200 litres
  - Ability to use disposable vessels up to 200 litres with an Allegro Mixing System
  - Nitrogen purging throughout the manufacturing process
- Grade A Filling zone
  - B+S Syringe Filling machine including:
    - Automatic removal of wrap from the tubs of empty syringes
    - Automatic lid removal from the tubs
    - Automatic dosing and bung insertion
    - Disposable filling pathway to minimise contamination risk
    - Nitrogen overlay during bung insertion
- Fedegari Autoclave for sterilisation of porous loads and terminal sterilisation of syringes where required
- Semi-automatic inspection
- Automatic rod insertion and labelling
- Hand packing of syringes
- Serialisation is available.



## Sterilisation

- Ability to produce both aseptic and terminally sterilised pre-filled syringes.

## UNIQUE SELLING POINTS:

- ★ Ability to handle large volumes of controlled drugs
- ★ PFS facility has passed an FDA pre-inspection
- ★ Experience in providing pharmaceuticals in many territories around the world
- ★ Space available for additional lines.