



DELPHARM

PREFILLED SYRINGES



A FULL RANGE OF SERVICES

Development from scratch to commercial manufacturing through IMP (Investigational Medicinal Product) manufacturing

Small and large molecules
Highly potent compounds
From 0.2 ml to 50 ml

Batch size from 1L to 500L
Minimum batch size: 100 units
Single-use or stainless steel tank

New and state of the art equipment

Regulatory affairs support

Type of syringes:

- Glass & polymer

Type of administration:

- Parenteral
- Ophthalmic
- Intra-nasal
- Intra-tympanic



Why choose prefilled syringes dosage forms?

Single use device

Easier to administer with dose accuracy and avoid medication errors

DEVELOPMENT

Large & small molecules
Highly potent compounds

Formulation and process development
Analytical method development & validation
Clinical batches manufacturing from phase 1 to phase 3



Type of formulation:

- Aqueous based solutions
- Emulsions
- Oil based solutions

Precise machines for stoppering PFS (GMP and non GMP)



Stabilities studies: all ICH conditions
In house microbiological testing
Complete testing



MANUFACTURING

Industrialization experience in transfers

From 0.2 ml to 50 ml
Yearly capacity: 25 - 30 millions syringes (for 1ml format)
Flexibility on volumes with stainless steel & single use
Storage capacity from -40°C to 2-8°C
Automatic visual inspection



Full cardboard packaging line
Carton trays
1 to 10 syringes per pack
Serialization & Aggregation



EMA
ANVISA
PMDA
FDA on request

