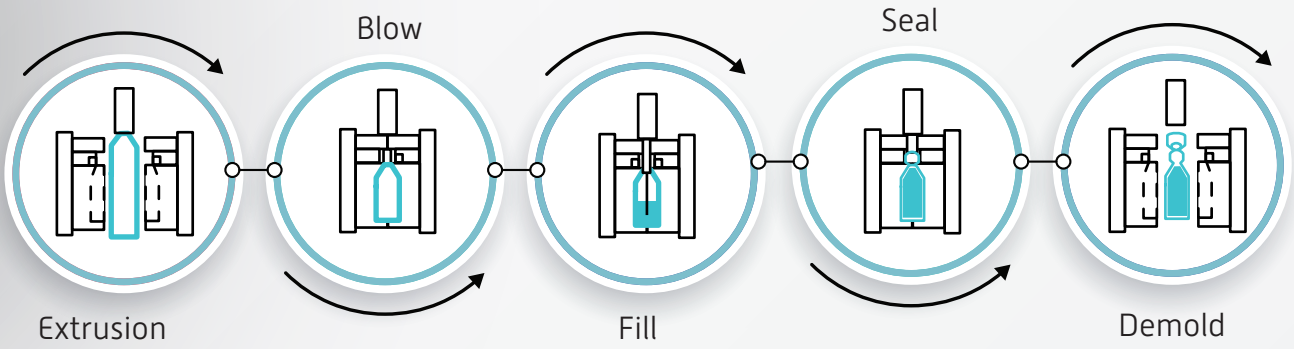
Blow-Fill-Seal Technology
Temperature management

Blow-Fill-Seal (BFS) is an Advanced Aseptic process for which temperature management is essential. It performs the primary packaging for a wide product variety: nebulized inhalation drugs, ophthalmic OTC products and drugs, and injectable products.

THE BLOW-FILL-SEAL PROCESS



Plastic is extruded at 170 – 220°C depending on the resin being used. The cooling process starts as soon as the plastic parison leaves the

The temperature controlled metal copper alloy moulds further continue the cooling process as they close and form the primary container.

The product filled into the container provides final plastic cooling process.



The polyethylene (plastic) for BFS is extruded at very high temperatures, which ensures its sterility. The BFS stages are carried out under a sterile air shower. The medicine in the unit-dose is therefore sterile by construction.

THE STABILITY CHALLENGE

Most biological products are sensitive to heat at some level (including biological substances such as vaccines or monoclonal antibodies). Many parameters influence the temperature of the formulation inside a BFS process. Success was found by actively in controlling the product temperature from bulk tank to point of fill.

WHAT IS THE SOLUTION?

Every biological product should be tested. At Unither, our R&D team can operate different tests to see how your formulation reacts.

1. 1st tests with water have been done to allow us to find the most influential factors of the BFS process and to allow us to distribute a solution at low T°C
2. A 2nd test was carried out with a type of biological molecule and the analyses are in progress
3. Other tests are under process, in order to bring new useful data

HOW CAN WE COLLABORATE?

Either an existing product with new packaging (interactions with the plastic) / compatibility test of the product with single doses (specifications) / product - polyethylene interactions
Or a product in development with BFS packaging



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FIRST BLOW-FILL-SEAL WORLDWIDE LEADER

Capacity
4,5 Billion SDU / year
Rapid scale-up capacity

Unique offer
Worldwide location &
Dual sourcing supply

5 manufacturing sites
- Amiens (France)*
- Coutances (France)*
- Nanjing (China)
- Gannat (France)
- Rochester (USA)

* vaccine manufacturing

Development & Analytics
- BFS dedicated development team
- Large expertise
- Pilot workshop

Authorizations
- FDA (USA),
- EMEA (Europe),
- ANVISA (Brazil),
- SKFDA (South Korea),
- and most of other authorities worldwide

TOP ADVANTAGES

- Less process steps
- Unbreakable
- Advanced & safe aseptic filling process
- Sterile
- Competitive costs