

Large-scale filling line + 10.2 m² freeze dryer



Specifications

Filling line (Groninger)

- Vial washing machine
- Depyrogenisation oven
- 4 Needle filling machine (incl. 100% IPC + stoppering)
- Capping machine

Capacity

- Liquids: up to 500L+/ batch
- Freeze-dried: up to 200L/batch
- Up to 40 million vials/year (2 RDIN, liquid)
- Up to 4 million vials/year (2 RDIN, freeze-dried)
- Speed: up to 11.520 vials/hr (2 RDIN)
- Vial sizes: 2 RDIN up to 50 RDIN vials

Lyophilizer (HOF)

- 10.2 m²
- Automated loading/unloading
- 7 shelves



EMA and US-FDA
certified facility



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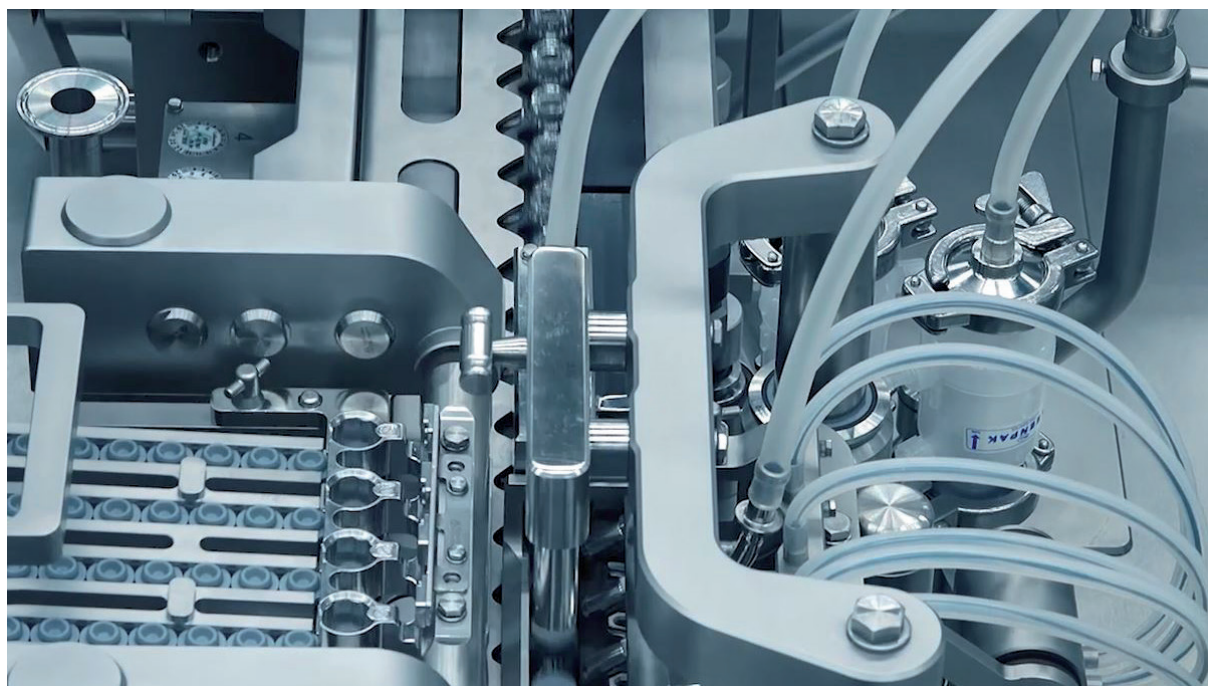
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Indicative maximum batch sizes (*)

Vial size	Liquid product	Lyophilized product
2 RDIN	57,000 – 150,000	44,900
6 RDIN	57,000 – 150,000	23,200
10 RDIN	50,000 – 150,000	19,600
20 RDIN	25,000 – 100,000	12,600
25 RDIN	20,000 – 80,000	12,600
50 RDIN	10,000 – 40,000	6,800

(*) Actual batch size depends on requested filling volume/vial and scale of production.
Examples are based on a 50% filling volume/vial (e.g. 25 ml fill in a 50 RDIN vial)



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