



DecFill® Aseptic Filling Line: True End-to-End Solutions From Molecules to Final Dosage Forms





DecFill® aseptic filling lines are designed to offer easy to operate systems optimizing production and minimizing change over time. From manual to fully automated lines, Dec offers comprehensive solutions for small and laboratory to highly flexible production scale filling lines suited for a wide range of primary packaging including double-chamber syringes.

By using standard modules, DecFill® solutions are configured to meet a wide range of product and customer requirements. These include de-bagging, de-lidding and de-nesting units and various other options to accurately fill liquids, powders and gels into the various containers.

To ensure highest process performance within a controlled environment, DecFill® equipment can be integrated into the required containment systems such as an o-RABS or an aseptic isolator.

Dec Experience



From standard to custom-tailored equipment solutions, Dec provides end-to-end solutions including aseptic filling for both liquids and powders.

Dec's engineered microdosing, filling and containment system technologies are designed to meet your particular needs for sterile primary packaging. Our filling solutions are cGMP compliant, perfectly adapted to each specific process requirements and accurately designed to comply with the most recent revisions of the EU GMP Annex 1: Manufacture of Sterile Medicinal Products guidelines.

DecFill® products can be easily combined and supplied with up- & downstream processing solutions from the raw material handling to the final dosage form, including continuous reaction, crystallization, filtration, drying, blending, micronizing and sampling.

Controls



Production lines can be supplied with various control options such as FDA 21 CFR Part 11, Audit Trail, batch recording and reporting.

Documentation & Support



Dec has years of experience in providing qualification documentation and support during projects: Therefore, we can support you with creating design, verification, qualification and validation documentation and provide support during the execution of documents.

Filling Lines

Product Container Dosing Range

Vials¹ (2–100 ml), Syringes¹ (0.5–20 ml), Cartridges¹ 0.5–20 ml, Dual Chamber Syringes¹, Sachets / Pouches, Special Packaging

Capacity [max ppm]²: 300 ppm



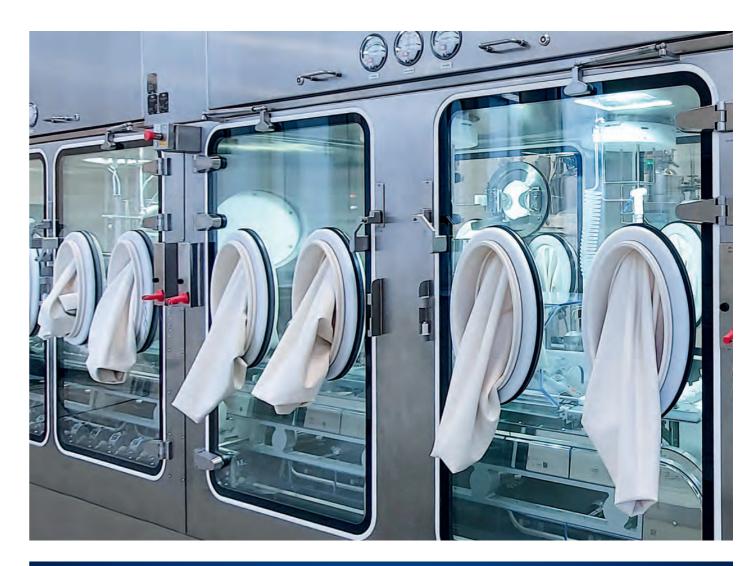
Process Options		
	Vials	Syringes
Gross Net Weighing	•	•
Gas Flushing	•	•
Liquid Filling	•	•
Powder Filling	•	•
Stoppering	•	•
Half Stoppering for Freeze Drying	•	
Aluminum Capping	•	
LLA Capping		•
Washing/Drying	•	•
Printing/Scanning	•	•

Powder Filling Techniques μPTS Technology flexPTS sPTS Auger system Principle Volumetric by Volumetric by Volumetric by Volumetric by Auger rotation and pre-defined chamber pre-defined chamber pre-defined chamber accurate level control **Dosing Range** 1-500 mg 200 mg-10 g 100 g+ 20 mg-5 g

Liquid Filling Techniques				
Technology	ВоМа	Peristaltic Pump	(Rotary) Piston Pumps	Pinch Valve Net weight
Principle	Volumetric displacement	Positive displacement	Positive displacement	Pressure/Gravity displacement







Containment – Barrier Technology			
	o-RABS	Aseptic Isolator cRABS (Liquid)	Aseptic Isolator cRABS (Powder/Liquid)
Purpose	Product Protection	Product Protection	Operator and product protection
Airflow	Uni-Directional	Uni-Directional with recirculation through double visors	Uni-Directional with recirculation through terminal exhaust filters
Access to inside	Gloves or opening doors	Gloves through double air return visor	Gloves
Decontamination	Hand sanitization	H ₂ O ₂ gassing	H ₂ O ₂ gassing
Characteristics	Air handling IN/OUT from cleanroom Background cGMP ISO6	Higher level Product Protection SAL-6 Background cGMP ISO 7/8 Separate HVAC unit	High level of Product & Operator Protection SAL-6 Background cGMP ISO 7/8 Separate HVAC unit

¹ Optional nested ready-to-use vials, syringes, Dual Chamber Syringes, cartridges

² ppm = products per minute; depending on the number of filling modules, product containers and final machine configuration

³ Based on water

DecFill® LAB (Laboratory)



Technical Specifications	
Container placement	Manual
Drug type	Liquid/Powder
Product container dosing range	
Vials	2-100 ml
Syringes	0.5-20 ml
Dual Chamber Syringes	
Bottles	
Cartridges	•
Ready-to-use	•
Sachets / Pouches	
Special Packaging	
Capacity [max ppm] ¹	3
Containment systems	
oRABS	•
Isolator	•
Container transport	Manual
IPC / Check weighing	•
Stoppering and/or (screw)capping	•
Audit trail / batch reporting	
GDP documented design verification	•

DecFill® MB (Micro Batch)



Technical Specifications	
Container placement	Manual
Drug type	Liquid/Powder/Gel
Product container dosing range	
Vials	2-100 ml
Syringes	0.5-20 ml
Dual Chamber Syringes	•
Bottles	
Cartridges	0.5-20 ml
Ready-to-use	•
Sachets / Pouches	•
Special Packaging	•
Capacity [max ppm] ¹	10
Containment systems	
oRABS	•
Isolator	•
Container transport	Robotics
IPC / Check weighing	•
Stoppering and/or (screw)capping	•
Audit trail / batch reporting	•
GDP documented design verification	ı •

DecFill® SB (Small Batch)



Technical Specifications	
Container placement	Semi-/Automatic
Drug type	Liquid/Powder/Gel
Product container dosing range	
Vials	2-100 ml
Syringes	0.5-20 ml
Dual Chamber Syringes	
Bottles	
Cartridges	0.5-20 ml
Ready-to-use	•
Sachets / Pouches	
Special Packaging	•
Capacity [max ppm] ¹	60
Containment systems	
oRABS	•
Isolator	•
Container transport	Indexing-intermittent
IPC / Check weighing	•
Stoppering and/or (screw)capping	•
Audit trail / batch reporting	•
GDP documented design verificatio	n •

DecFill® PS (Production Scale)



Technical Specifications	
Container placement	Automatic
Drug type	Liquid/Powder/Gel
Product container dosing range	
Vials	2–100 ml
Syringes	0.5-20 ml
Dual Chamber Syringes	•
Bottles	
Cartridges	0.5-20 ml
Ready-to-use	•
Sachets / Pouches	•
Special Packaging	•
Capacity [max ppm] ¹	300
Containment systems	
oRABS	•
Isolator	•
Container transport	Linear-individual
IPC / Check weighing	•
Stoppering and/or (screw)capping	•
Audit trail / batch reporting	•
GDP documented design verification	•

DecFill® LAB Ideal for Laboratory Use on a Workbench for Liquids and/or Powders



DecFill® LAB for liquids

DecFill® LAB (Laboratory)

DecFill® LAB is ideal for workbenches or the integration into existing containment systems (o/cRABS).

The product containers are placed manually by an operator. This tabletop unit is capable of handling a variery of container types such as Ready-to-Use (RTU) systems, vials, cartridges, and syringes.

Features & Options

Manual container placement

Various containers filling - syringes, cartridges, vials etc.

Tabletop unit ideal for workbench or in containment

Recipe control via HMI, data collection by USB download

Highly accurate, patented filling technologies for powders and liquids

Automatic check weighing and stoppering

Various aseptic Dec containment systems (oRABS, Isolators)



DecFill® LAB for powders

DecFill® MB Robotic solutions for handling and transporting various container types



Fully robotized solution for product container handling

DecFill® MB (Micro Batch)

DecFill® MB integrated into Dec's engineered containment system is capable of processing aseptic and high potent micro-batches suitable for R&D, clinical trials and laboratories.

The product containers are handled between the modules by a state-of-the-art robotic system. Due to Dec's patented liquid filling and powder dosing technologies, DecFill® MB performs filling with high accuracy.

Features & Options

Robotic moving the product between the modules

Capable of handling multi-containers in one platform – RTU systems, vials, cartridges, syringes, etc.

Flexible, modular and compact

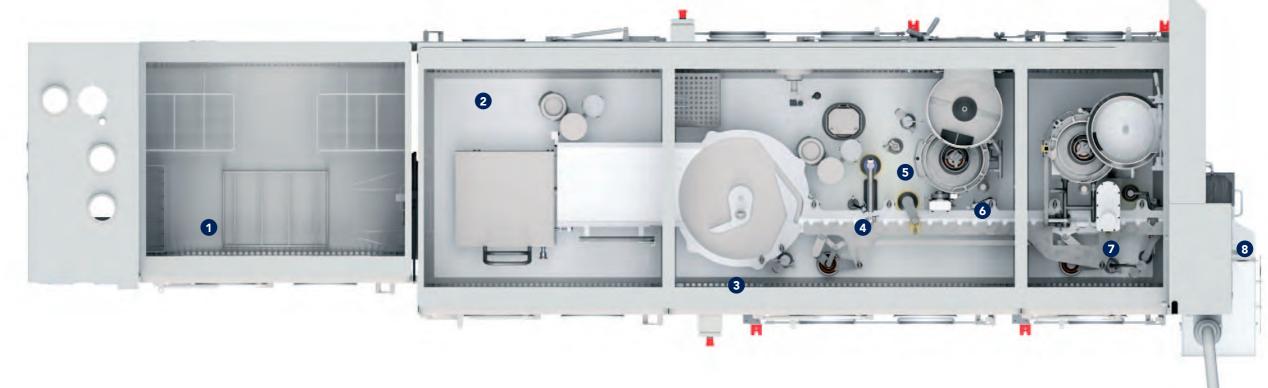
Highly accurate patented liquid filling and powder dosing technologies

Various aseptic Dec containment systems (oRABS, Isolators)



DecFill® SB Highly accurate, patented filling technology for powders, liquids and gels

- 1 Fast Gassing
 Decontamination of
 RTU products de-bagging
- 2 Tray-offloading
- 3 Buffer Turntable
- 4 Main Transport
- 5 Liquid Filling & Check Weighing
- 6 Rubber Stopper
- 7 Capping
- 8 Outfeed & Reject





DecFill® SB (Small Batch)

DecFill® SB aseptic filling line is designed for small batches and ideal for small scale aseptic production. Its modular, simple and compact design is suitable for limited cleanroom space while maximizing the filling efficiency.

With implementation of index intermittent transport system, the walking beam moves containers to the next position. Due to Dec's patented liquid filling and powder dosing technology, DecFill® SB performs filling with high accuracy.

VHP decontamination: Fast Gassing Airlock integrated design for tray offloading

Features & Options

Small scale aseptic production

Various solutions for the supply of packaging materials

Integrated environmental monitoring

Highly accurate, patented filling technologies for powders, liquids and gels

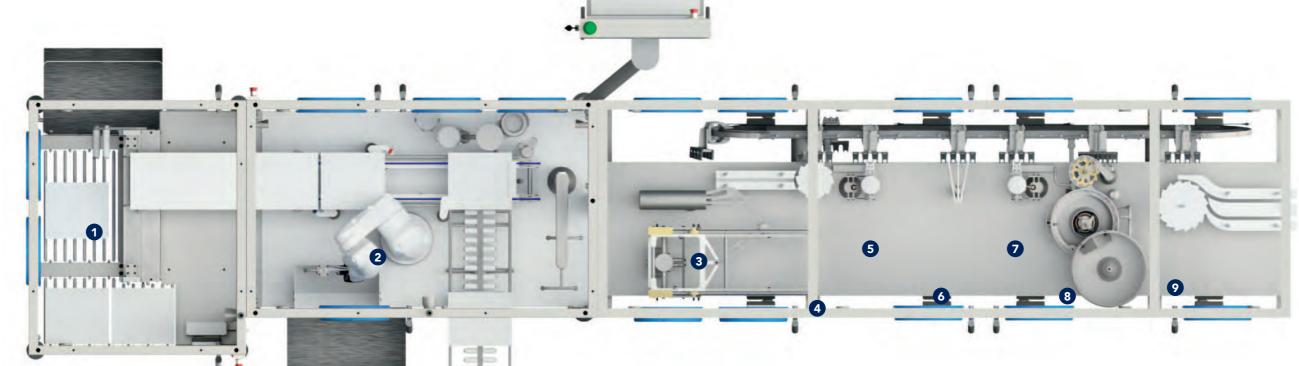
Various aseptic Dec containment systems (oRABS, Isolators)

Highly integrable, reflecting Dec's continuous manufacturing single source solutions



DecFill® PS Fully automatic and modular production scale

- 1 De-Bagging
 Removing outer bag of
 Ready-To-Use products
- 2 De-Lidding
 Removing lid of
 Ready-To-Use products
- 3 De-Nesting
- 4 Individual Product Holder Moving the container with variable speed to any programmable position
- 5 Gross Weighing
- 6 Filling
- 7 Net Weighing
- 8 End-Stoppering
- 9 Outfeed



DecFill® PS (Production Scale)

DecFill® PS aseptic filling line is designed for improved accessibility and reduced cleanroon space while maximizing the efficiency in the filler.

With implementation of flexible magnetic linear transport system, DecFill® PS is capable of handling multi-containers in an isolator such as Ready-to-Use (RTU) systems, vials, cartridges, syringes, sachets/pouches, and special packaging with flexible speed and motion.



Flexible Main Transport

Maximize filling efficiency by handling multi-container in one filling line

Slim machine design for improved accessibility and reduced cleanroom space

Suitable for all RTU systems, vials, cartridges, syringes, sachets/pouches and special packaging

Fully automatic and modular production scale enables a wide variety of configuration options

Highly accurate, patented filling technologies for powders, liquids & gels







At Dec, customer service is an important part of every project. We accompany our customers over the entire life cycle of their project. Dec's support team will provide professional support to any problem worldwide.

All Dec equipment is designed for optimal performance and durability. However, parts of every machine are subject to wear and tear. We offer spare parts and various maintenance models to enhance production efficiency and productivity.

Dec provides various training sessions from workshops on existing workplace equipment to teach operators how to effectively do their job to inhouse seminars or convenient webinars.

Short facts

The depth of Dec's knowledge and their ability to develop innovative new technologies make them an invaluable partner for both multinationals and specialist organizations. With true worldwide coverage through subsidiaries in Switzerland, Germany, Great Britain, Ireland, Netherlands, Poland, USA, India, China, its recent acquisitions of advanced containment and aseptic solution provider Extract Technology and AWL, specializing in continous manufacturing solutions as well as agents covering more than 60 countries, the Dec Group provides its customers with global expertise in process containment technologies and a reliable network for local support.



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