Filling and Closing Machines
Vials and Infusion Bottles for Liquid and Powder
Optima Pharma excels in meeting the pharmaceutical industry’s highest expectations with the four brands Inova, Kugler, Klee and Metall + Plastic. Optima Pharma offers a diversified and innovative portfolio of filling and packaging machines for sterile and non-sterile pharmaceutical liquids and powders in addition to supplying lyophilization and isolation technology.

Optima Pharma is internationally recognized by the pharmaceutical industry for machine efficiency and precise realization of complex turnkey projects.

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Optima Pharma washers are completely made of stainless steel, non-corrosive, pharma-conform plastics. The washers are designed in accordance with cGMP standards and have a wide variety of usage. Product contact parts are easy to clean and designed to facilitate accessibility. For the cleaning and treatment of containers, all cleaning media customary to the pharmaceutical industry can be used.

Two different designs are available:
- Tunnel Washers
- Rotary Washers

**Tunnel Washer**

Fully-automatic tunnel washers are designed for automatic and continuous cleaning of vials and infusion bottles. Washers are available with or without ultra-sonic pre-treatment and the connection to a sterilization tunnel can be performed with ease. Output up to 24,000 containers/hour with extremely gentle treatment of your containers.

**Rotary Washer**

Fully-automatic rotary washers for the treatment of vials and infusion bottles. Washers are available with or without ultra-sonic pre-treatment and the connection to a sterilization tunnel can be performed with ease. Output up to 24,000 containers/hour. The transport can be either cycled or continuous by means of one or several laned transport grippers.

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**Technical Data:**

<table>
<thead>
<tr>
<th>Tunnel Washer</th>
<th>Rotary Washer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>12</td>
</tr>
<tr>
<td>Machine type</td>
<td>Fully-automatic</td>
</tr>
<tr>
<td>Containers</td>
<td>Vials and infusion bottles</td>
</tr>
<tr>
<td>Container size range:</td>
<td></td>
</tr>
<tr>
<td>Neck opening</td>
<td>&gt;7 mm</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>20–52 mm up to 104 mm</td>
</tr>
<tr>
<td>Max. height</td>
<td>9–20</td>
</tr>
<tr>
<td>Spray positions</td>
<td></td>
</tr>
<tr>
<td>Output (depending on container shape and size)</td>
<td>up to 24,000 containers/h</td>
</tr>
<tr>
<td>Cleaning sequences</td>
<td>10</td>
</tr>
<tr>
<td>Spray duration per station</td>
<td>1.9”–7.5”</td>
</tr>
<tr>
<td>Max. number of recirculation pumps</td>
<td>2</td>
</tr>
<tr>
<td>Infeed of containers</td>
<td>Carrier pockets</td>
</tr>
</tbody>
</table>
Optima Pharma sterilization tunnels are part of a complete aseptic filling line designed to sterilize and to depyrogenate glass containers such as injection and infusion bottles and syringes – from cleaning to aseptic filling a continuous operation mode in a clean room environment. The tunnel program consists of Laminar-Flow (LF) hot air tunnels, and infrared/hot air combination tunnels. Depending on your application, Optima Pharma has the right tunnel for you.

The cleaned containers are transported through the infeed, which is equipped with Laminar Flow, into the sterilization area – the heating zone. The containers are heated to a defined temperature in order to ensure secure sterilization and depyrogenization. Sterilization can be performed by means of LF-hot air, or a combination of hot air and infrared quartz glass heaters. Both of the sterile systems are designed for defined applications. The tunnels are equipped with state-of-the-art automation and communication systems. This ensures detailed data recording and tracing of temperatures.

### Technical Data:

<table>
<thead>
<tr>
<th>Type</th>
<th>SHT/SHT IR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conveyor belt width</td>
<td>300, 450, 600, 800, 1250, 1600</td>
</tr>
<tr>
<td>Transport height</td>
<td>900 mm +/- 25 mm</td>
</tr>
<tr>
<td>Filter system</td>
<td>HEPA filters - H13/H14</td>
</tr>
<tr>
<td>Output</td>
<td>up to 44,000/h, bei 10H (depending on container)</td>
</tr>
<tr>
<td>Heating temperature output</td>
<td>20 – 200 KW (depending on output)</td>
</tr>
<tr>
<td>Cooling power</td>
<td>0.3 – 15 m³/h</td>
</tr>
<tr>
<td>Sterilizable cooling zone</td>
<td>Optional</td>
</tr>
</tbody>
</table>

- Automatically lockable and heated gas-tight tunnel door with sealing at the outfeed of the tunnel
- Isolation of the cooling zone
- Special fans
- Separate closed cooling circuit with recirculation pump and mixing valve for the sterilizable cooling zone
- Sterilization program for sterilization implementing
Modular and compact designed machines according to cGMP standards with minimum space requirement – the fully-automatic Optima Pharma filling and closing machines are used for a wide range of applications, are designed for your individual needs and can be easily retrofit.

In laboratories and R&D the demands on technical equipment for the manufacture of sterile and aseptic products are continuously increasing.

Optima Pharma has a leading position in the field of sterile filling technology. To meet the market challenges a custom-made integral solution for the processing steps of:

- Washing
- Sterilizing
- Filling
- Stopper insertion
- Crimping (optional)

has been developed.

This state-of-the-art compact concept meets all known requirements regarding technological design and the ever-increasing cGMP regulations. The filling machine is also available as a stand-alone model.
Type VFVM 3000/4000

A fully-automatic filling and closing machine for vials and infusion bottles. Compact designed machines according to cGMP standards – machines are used for a wide range of applications and designed for your individual needs and can be easily retrofitted.
In order to decide on the most suitable filling system for sterile pharmaceutical liquids and powders, different factors must be taken into consideration:

- The diverse product characteristics
- Environmental conditions of the filling process
- Given format diversities
- The specified output
- The specified dosing accuracy

The following systems are considered:

**Time Pressure**

Time pressure dosing system is the most frequently installed in pharmaceutical applications.

**Peristaltic Pumps**

Peristaltic pumps enjoy a high preference in biotechnological applications.

**Disposables**

Disposable systems mark the future trend in the world of drug manufacturing and play a huge role in the development of new processes and products.

**Powder dosing**

Auger filling for sterile filling of powders.

**Rotary Piston Pumps**

Self-sucking rotary piston pumps are applied for a wide range of products.

**Mass Flow Meter**

Mass flow meter is usually installed in applications where product viscosity is temperature-sensitive.

Type VFVM

7000 / 10000 / 18000 / 2400

A fully automatic filling and closing machine to process vials and infusion bottles from 0.1 ml to 500 ml. Output 500 - 27,000 objects/h, depending on product viscosity and fill volume.

Advantages of the rake transport system versus the alternative system for machines with a medium output: The vials and infusion bottles are not processed or filled in a star wheel or on a conveyor belt. Easy access to the individual station due to the narrow design of the machine. The vials/infusion bottles are continuously secured and centered during transport ensuring that the vials or infusion bottles will not topple over or interchange. The linear transport system permits better accessibility for cleaning and monitoring of processes. The absence of a transport star wheel allows for faster and safer change of size parts.

Filling and Closing Machines

Flexibility by Means of a Modular Design

Filling and Closing Machines

Our Dosing Systems At a Glance
Optima Pharma is one of the world’s leading organizations for pharmaceutical filling, packaging and freeze drying technologies but also houses a team of skilled integrators ranging from designers, project engineers to the most qualified technicians and programmers. This in-house expertise and know-how allows Optima Pharma to act as a one-stop-shop where customers benefit from sourcing a wide range of solutions from a single provider.

Why OPTIMA pharma?

► Leading position in sterile, aseptic filling, freeze drying and clean room technology
► Custom-tailored solutions for even the most complex projects
► One-stop-shop
► State-of-the-art GMP compliant machines
► Reliable, goal-oriented, efficient, innovative and flexible
► Comprehensive service packages

### Technical Data:

<table>
<thead>
<tr>
<th>Type</th>
<th>VFVM 2000</th>
<th>VFVM 3000</th>
<th>VFVM 4000</th>
<th>VFVM 7000</th>
<th>VFVM 10000</th>
<th>VFVM 18000</th>
<th>VFVM 24000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine description</td>
<td>Compact laboratory machine (Stand alone model or in line integration)</td>
<td></td>
<td></td>
<td>Fully automatic filling and closing machine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Containers</td>
<td>Vials</td>
<td>Vials and infusion bottles</td>
<td>Vials and infusion bottles</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Infed</td>
<td>Manual onto turn table From sterilization tunnel onto turn table</td>
<td>Conveyor belt Turn table</td>
<td>Conveyor belt Turn table</td>
<td>Conveyor belt Turn table</td>
<td>Conveyor belt Turn table</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filling volume</td>
<td>0.1–100 ml</td>
<td>0.1–250 ml</td>
<td>0.2–250 ml</td>
<td>0.1–1.5 ml (4-lane)</td>
<td>0.1–100 ml (2-lane)</td>
<td>0.1–500 ml (1-lane)</td>
<td>0.1–100 ml</td>
</tr>
<tr>
<td>Container size range</td>
<td>1-lane: Ø 14.5–52 mm Height: max. 110 mm</td>
<td>1-lane: Ø 16–66 mm (36 mm 2-lane) with infed scroll Ø max. 30 mm Height: max. 75 mm</td>
<td>Round containers: up to Ø 100 mm Height: max. 220 mm</td>
<td>Transport star wheel, Ø max. 24 mm (4-lane) Ø max. 52 mm (2-lane) Ø max. 86 mm (1-lane)</td>
<td>28–500 IU Ø 14.5–52 mm Height: 30–105 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output (Containers/h)</td>
<td>up to 45 (up to 7,000 2-lane)</td>
<td>up to 4,200 (up to 7,000 2-lane)</td>
<td>up to 4,200 (up to 7,000 2-lane)</td>
<td>up to 7,200 (up to 12,000 4-lane)</td>
<td></td>
<td></td>
<td>up to 24,000 up to 30,000</td>
</tr>
<tr>
<td>Operators</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>IPC</td>
<td>100 % statistical</td>
<td>100 %</td>
<td>100 % statistical</td>
<td>100 % statistical</td>
<td></td>
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</tr>
</tbody>
</table>
The manufacturing as well as the handling of pharmaceutical products not only requires a high degree of competence by all parties, but also meticulous handling of the products.

In 2005, Klee GmbH joined Optima. Thanks to many years of specialization, as a brand of Optima Pharma, Klee offers a comprehensive and technically leading product range:

- Sterile freeze drying plants for the pharmaceutical industry – from high tech pilot plants to highly efficient production plants. A seamless scaled version of the pilot plant to a full size production plant is guaranteed.
- Fully automatic loading and unloading systems for vials, ampoules, syringes or bulk loading; also in connection with RABS or isolator technology.
- Upgrades of machines not fulfilling state-of-the-art technology or those who are no longer up to date with the current regulations.
- Consulting, training, service, and maintenance.

Innovative solutions tailored to the customer’s requirements, e.g. a loading cart freely mobile in a room
- Loading row by row, shelf by shelf, frame by frame
- Fully automatic handling of vials, ampoules, syringes and magazines
- Isolator or RABS technology

Processing of solvents in compliance with ATEX directive

Flexible and customer focused layout concepts
- Shelves which display an extremely even temperature distribution
- Fully automatic filter test units (WIT)
- Steam sterilization at 1.5 bar
- \(H_2O_2\) sterilization
- Clean In Place (CIP) with a cleaning process that can be validated
- Visualization with Klee Lyomatic and standard applications
- Modern support /remote control
- Processing of solvents in compliance with ATEX directive

Sterilizable freeze drying plants for the pharmaceutical industry – from high tech pilot plants to highly efficient production plants. A seamless scaled version of the pilot plant to a full size production plant is guaranteed.

- Loading and freeze drying
- Greater benefits for the user

Highlights

**Freeze Drying**

- Flexible and customer focused layout concepts
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- Steam sterilization at 1.5 bar
- \(H_2O_2\) sterilization
- Clean In Place (CIP) with a cleaning process that can be validated
- Visualization with Klee Lyomatic and standard applications
- Modern support /remote control
- Processing of solvents in compliance with ATEX directive

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- Loading row by row, shelf by shelf, frame by frame
- Fully automatic handling of vials, ampoules, syringes and magazines
- Isolator or RABS technology

**Loading and Unloading Systems**
Machines designed to close a wide variety of containers for the pharmaceutical industry. Even in the basic machine, several design details are utilized, which sets us apart from the standard:

- Electronic and central height adjustment
- Selectable torque function
- PLC-guided size part change

The following process steps are possible:

- Stopper insertion
- Crimping
- Screwing
- Insertion of droppers, spray pumps and pipettes
- Placing of press-on caps

Technical Data:

<table>
<thead>
<tr>
<th>Type</th>
<th>VVM 211</th>
<th>VVM 3000</th>
<th>VVM 4000</th>
<th>VVM 7000</th>
<th>VVM 2400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine description</td>
<td>Fully automatic closing machine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Containers</td>
<td>Vials and infusion bottles</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infeed</td>
<td>Turn table with feeding plate</td>
<td>Conveyor belt, Transport scroll, Turn table</td>
<td>Conveyor belt, Turn table</td>
<td>Table rotative</td>
<td>Table rotative</td>
</tr>
<tr>
<td>Container size range</td>
<td>Ø 15 – 52 mm Height: 30 up to 105 mm</td>
<td>Ø 15 – 66 mm Height: 30 up to 140 mm</td>
<td>Ø 15 – 100 mm Height: 30 up to 200 mm 1-lane</td>
<td>Ø 40 – 86 mm Height: 68 – 147 mm 1-lane</td>
<td>Ø 15 – 52 mm Height: 35 up to 105 mm (10-lane)</td>
</tr>
<tr>
<td>Ø 15 – 52 mm Height: 35 up to 105 mm (10-lane)</td>
<td>Ø 15 – 100 mm Height: 30 up to 200 mm 1-lane</td>
<td>Ø 40 – 86 mm Height: 68 – 147 mm 1-lane</td>
<td>Ø 15 – 52 mm Height: 35 – 105 mm 2-lane</td>
<td>Ø 40 – 86 mm Height: 68 up to 147 mm (8-lane)</td>
<td></td>
</tr>
<tr>
<td>Output (containers/h)</td>
<td>45/min 1-lane up to 4,200 1-lane (up to 7,000 2-lane)</td>
<td>up to 4,200 1-lane up to 7,000 2-lane</td>
<td>up to 3,600 1-lane up to 7,200 2-lane</td>
<td>up to 14,000 8-lane up to 27,000 10-lane</td>
<td></td>
</tr>
<tr>
<td>Operators</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Space requirements</td>
<td>0,7 m²</td>
<td>0,8 m² (without convey or belt, sorting and feeding devices)</td>
<td>1,4 m² (without convey or belt, sorting and feeding devices)</td>
<td>1,4 m² (without convey or belt, sorting and feeding devices)</td>
<td>1,6 m² (without convey or belt) sorting and feeding devices are integrated</td>
</tr>
</tbody>
</table>
An exact number of steady vials or bottles can be loaded with our fully automatic, high speed tray loader. Two/four trays are filled alternately, ensuring tray swapping without machine stop. By means of a conveyor belt equipped with a minimum accumulation sensor, the vials/bottles are fed into the infeed. Reciprocal interlocks at the infeed create an accumulation with the exact number of vials/bottles. The accumulated vials/bottles are transported in front of the pusher, with a stopping finger ensuring the correct placement of the vials/bottles. To prevent the vials/bottles from tipping over, a mechanically driven pusher with a counter guide maintains their placement. The number of cross pushers are counted, to ensure the exact equal amount of vials/bottles in each tray. The trays are secured against overload.

**Advantages**

The machine works according to the FIFO principle (First in – First out). During the process no vials remain on the conveyor belt.

### Technical Data:

<table>
<thead>
<tr>
<th>Type</th>
<th>M 2412</th>
<th>M 2424</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine Description</td>
<td>Fully-automatic Tray Loader</td>
<td></td>
</tr>
<tr>
<td>Number of trays</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Containers</td>
<td>Steady vials and bottles Diameter: 14.5 up to 78 mm Height: 30 bis 240 mm</td>
<td></td>
</tr>
<tr>
<td>Traying possibilities of vials/bottles</td>
<td>Width: 250 up to 500 mm Length: 300 up to 600 mm Width: 250 up to 400 mm Length: 300 up to 600 mm</td>
<td></td>
</tr>
<tr>
<td>Traying possibilities</td>
<td>No nesting Semi nesting Full nesting</td>
<td></td>
</tr>
<tr>
<td>Output (depending on container diameter and tray configuration)</td>
<td>Max. 12,000 pcs./h Max. 24,000 pcs./h</td>
<td></td>
</tr>
</tbody>
</table>
Clean Production

Clean production technology provides the basis to ensure a safe production environment for filling sterile drugs.

The filling technology provides for the precise dosing of drug products under the aspect of sterile product handling. Optima Pharma unites the required clean production technology with the state-of-the-art filling technology to help you market a high-value pharmaceutical product.

The portfolio of Optima Pharma and the brands Inova and Metall + Plastic offer three different technical air protection systems:

- Restricted Access Barrier System (RABS)
- Closed Restricted Access Barrier System (C-RABS)
- Isolator

Clean Production

At first glance, all three systems work as a clean room micro plant. But as far as technology and regulation are concerned, the differences are quite considerable and have to be assessed for each individual project. We would be happy to recommend the correct protection system suitable for your application.

Restricted Access Barrier System (RABS)

To restrict the operator access to the process area, our filling machines can be provided with RABS equipment as an option. The restricted access is in this case achieved by glove systems, and mock-up studies are used to determine in advance the gloves’ positions.

Ventilation concept

The required process air is taken from the machine environment and filtered by means of a HEPA filter. Variable speed-controlled ventilators supply constant air volume to the unit. Air distribution is achieved by means of a plastic diaphragm, which ensures uniform air distribution in the protected area with little turbulence.

System description / technical module

The technical module consists of high-quality stainless steel materials and is located above the protection module. It contains the complete technical air equipment, such as ventilators, filters, cleanroom illumination and air distribution diaphragm.

Protection module

The protection module consists of high-quality stainless steel materials. Doors, windows and other functional elements are integrated into the modular section framework, as required for the individual machine. Intervention in the protection module is achieved by means of glove accesses that are integrated into the glass doors (tempered safety glass (ESG)).

Closed Restricted Access Barrier System (C-RABS)

Isolator

Possible operation parameters

- Air speed
- Pressure regulation (option)
- Air temperature (option)
- Humidity
Turnkey Line Solutions
INOVA WM 12, SHT 12, VFVM 18000, VVM 2428 with outside washer, KLEE Freeze dryer, M+P Isolator

Vial Ø
24 mm

Output
up to 24,000/h

Features
- Cold loading via nitrogen curtain
- Empty vial inspection
- 5 double stacked peristaltic pumps
- Oxygen less than 1%
- Processing of toxic products

Production process
1 Product infeed, Vials
2 Washer
3 Sterilizing tunnel
4 Infeed turn table
5 Transport
6 Product infeed
7 Dosing system (peristaltic pumps)
8 Filling station
9 IPC
10 Sorting bowl for stopper
11 Stopper insertion
12 Reject
13 Freeze Dryer
14 Crimp module
15 Outside washer
16 Traying
Turnkey Line Solutions
INOVA WMR 2400, SHT 13, VFVM 18000, VVM 2428, 2 x RALUT, 2 x Klee Freeze Dryer D-30

Container size range
2R–25R (up to 10–lane)

Features
- Two Dosing systems:
  - Peristaltic pumps (CIP / SIP)
  - Time pressure (CIP / SIP)
- Fully automatic row by row loading and unloading
- Glass particle monitoring system
- Cap quality monitoring system

Active open RABS

Prozessablauf
1. Rotary washer
2. Sterilizing tunnel
3. In-Process Control
4. CIP/SIP Cabinet
5. Dosing module: Time pressure
6. Dosing module: Peristaltic pumps (optional)
7. Stopping module
8. Capping machine
9. RABS
10. Freeze dryer, RALUT
Processing Line for Vials under Isolator
INOVA WMR 600, SHT 19 S, VFVVM 7042, EVK 7000

Output
up to 5,400/h

Vial
10–500 ml

Minimized
product loss

100 %
In-Process Control

Features
- Minimal product loss in entire batch process
- Fast changeover time via fully automatic format change
- Disposable product path
- Reduced VHP decontamination cycles

Prozessablauf
1 Rotary washer
2 Sterilizing tunnel
3 In-Process Control
4 Dosing module
5 Stopping station
6 Capping module
7 Reject
8 Vial coding unit
9 Reject
10 Traying

Machines
- Rotary Washer, model WMR 600
- Sterilization tunnel, model SHT 19
- Filling and closing machine, model VFVVM 7042
- Vial coding unit, model EVK 7000

Filling and Closing Machine
- 4+2-lane peristaltic pump dosing system
- 100% IPC
- Redosing, Restoppering, Recapping, Repressing
- Rake transport system
- Disposable product path outside of isolator
- Pump outside of isolator, therefore changeover time of product contact parts is max. 15 minutes
- Print verification via camera
- Non-circular cap verification via camera
- Stopper height verification via camera

M+P Isolator
- Cleanliness class ISO 5
- Integrated material transfer chamber (MTC)
- Integrated M+P H2O2 generator RG 4
- Catalytic aeration process
Process reliability is also a question of service. Even the best machines and lines are subject to a certain extent of wear. With our team of experts and the worldwide available service network of the Optima Pharma, you will reduce the risk of machine downtime to a minimum. Additionally, a 24-hour hotline as well as an extensive spare parts supply within a very short time are at your disposal. Electronic spare parts catalogs, comprehensive technical documentation and operating instructions as well as the teleservice, facilitate the competent handling of trouble-shooting. Service already starts when commissioning the machine. The Optima Pharma offers you training specifically adapted to your requirements. Incidentally, it is not always necessary to invest in new machinery. Innovative machine upgrades and individual retrofitting packages of the Optima Pharma upgrade your machines to the state-of-the-art. Ask us for a service package meeting your requirements. It will be our pleasure to assist you.

Service
A Comprehensive Service Program

Contact Us
The Safety of a Strong Partner
More information:
www.optima-pharma.com