

SMART PWD

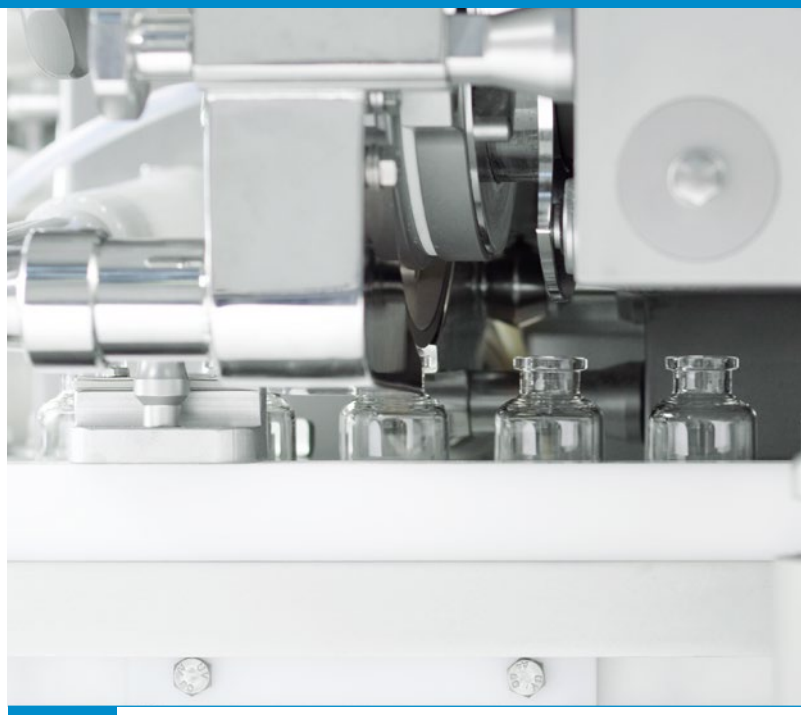
ASEPTIC POWDER FILLING AND STOPPERING MACHINE



SMART PWD ASEPTIC POWDER FILLING & STOPPERING MACHINE

THANKS TO INTELLIGENT SERVO TECHNOLOGY, THE MACHINE IS EXTREMELY USER-FRIENDLY AND FLEXIBLE IN ITS APPLICATION.

DESIGNED FOR cGMP COMPLIANCE, ALL MACHINE AREAS ARE EASILY ACCESSIBLE AND OPERATIONS ARE CLEARLY VISIBLE DURING PRODUCTION.



LAST GENERATION OF MEDIUM SPEED MICRODOSING MACHINE

The pharmaceutical packaging market is constantly advancing, requiring more and more flexibility in handling different product batches with high value products and at various production speed range requirements.

Specific dosing equipment must satisfy the most diversified requirements in terms of versatility, product protection, process safety and filling accuracy.

These aspects have been combined into the latest solution for the processing of sterile pharmaceutical powders: the new **Smart PWD Series**.

Conceived for modern manufacturing, safety and quality in powder microdosing, this innovative machine completes the IMA Life product portfolio in the sector.

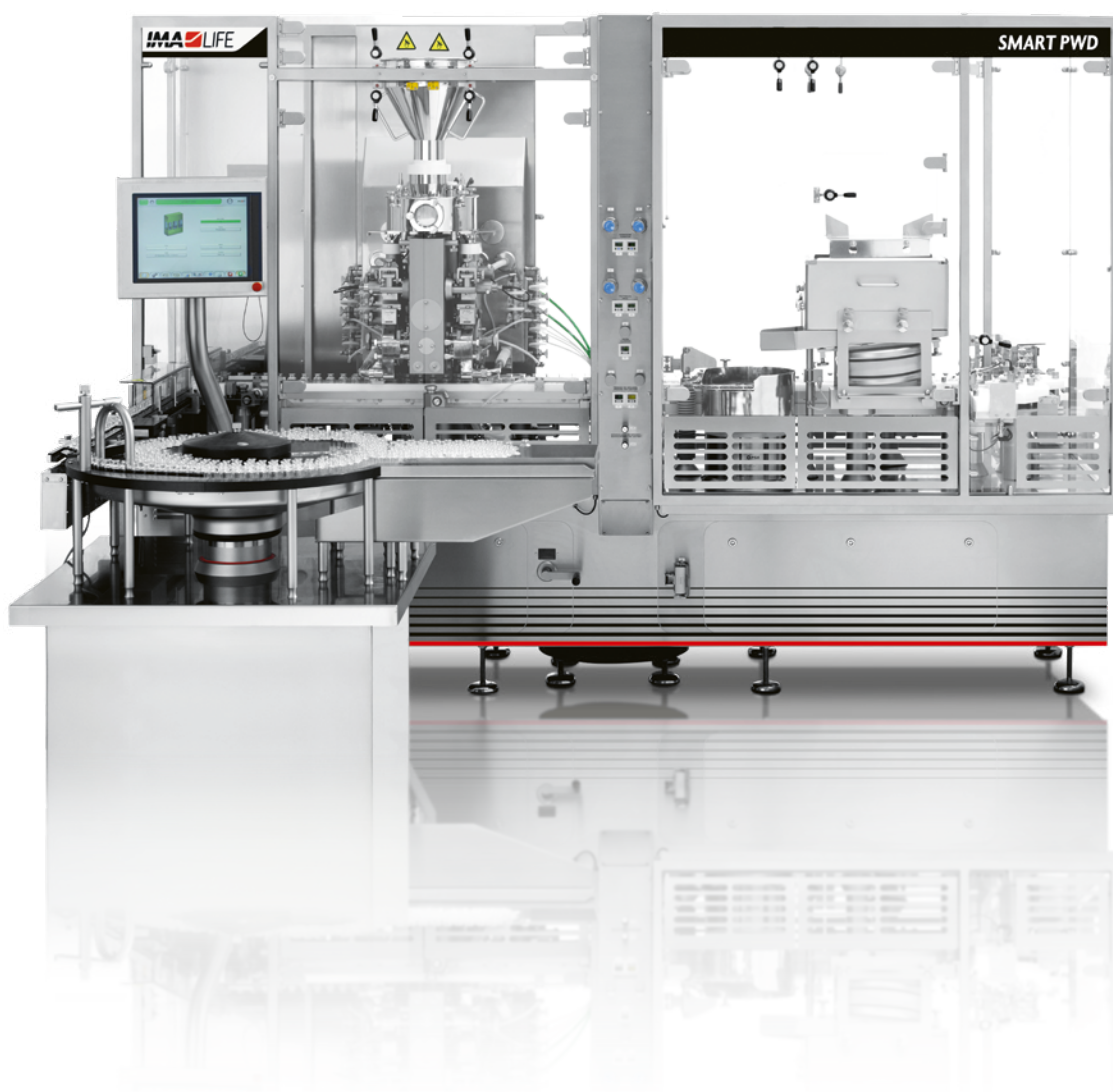
With intermittent motion and positive in-line transport system, Smart PWD not only processes difficult powders accurately, but also offers the possibility to simultaneously fill different types of pharmaceutical products inside the same vial.

Thanks to its reduced footprint dimensions the machine fulfils the highest requirements of flexibility and versatility: it's the right solution when space constraint is an issue. Its high technology profile makes it suitable for installation in conventional sterile room or under cRABS/ Isolator systems.





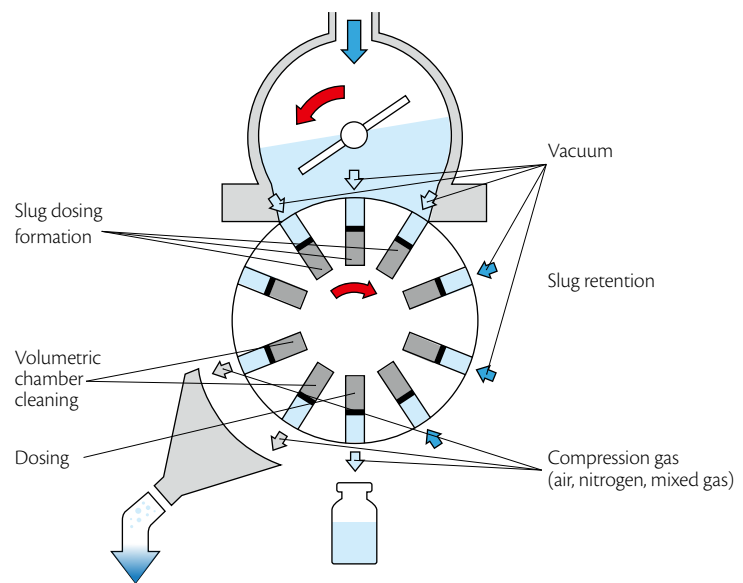
MORE THAN JUST COMPACT:
ITS REDUCED DIMENSIONS MAKE
SMART PWD PERFECTLY SUITABLE FOR
cRABS OR ISOLATOR INTEGRATION



SMART PWD DOSING SOLUTIONS & VACUUM TECHNOLOGY



Powder dosing unit with two dosing discs



Vacuum-pressure dosing steps

- ALL MATERIALS IN CONTACT WITH THE PRODUCT ARE BUILT IN AISI 316 L ST. ST., TEFLON OR SILICONE RUBBER AND CAN BE STERILIZED IN AUTOCLAVE.
- ALL HOPPERS ARE DISMOUNTABLE WITHOUT TOOLS.
- AUTOMATIC SIMULTANEOUS ADJUSTMENT SYSTEM OF DOSING DISC CHAMBER DEPTH WHICH, COMBINED WITH 100% IPC, DRASTICALLY REDUCES POWDER WASTE.



Dosing disc detail

EXCELLENCE IN FILLING: VACUUM-PRESSURE DOSING SYSTEM

The unpredictable nature of pharmaceutical powders makes it imperative to deliver a tight dose control in terms of strict dosage accuracy and repeatability, but also efficient sampling and precise check-weighing for proper dose verification.

Adjustability and adaptability of a dosing system are key features to face this challenge: **vacuum-pressure powder filling technology** is the dosing system commonly used when it comes to high-accuracy dosing requirements.

The Powder dosing unit consists of:

- Upper powder feeding hopper
- Lower hopper(s) with stirrer and powder level sensors
- Up to four dosing discs complete with 10 chambers each, with dosing pistons
- Vacuum/Compressed air circuit for powder ejection into vial and dosing chamber cleaning
- Dust removing system with cyclone dust recovery unit and dust removing aspirator
- Powder feeding unit (various options are possible, such as Customers' bins or bags)

Powder aspiration is from the lower hoppers and it is held by vacuum during disc rotation. In its lower position, the disc discharges the powder into the vial by means of sterile air. After dosing, the slot which has ejected the powder is cleaned by sterile air jets.

All utilities can be easily adjusted from the frontal "pushbutton panel" for slug formation, holding and ejection and for chamber slot cleaning.



SMART PWD CONTROL SYSTEM



Vial infeed detail



Dosages starting from 50 mg

The vials are constantly transferred through the machine by a pocket-fitted double comb system, moving the vials in a positive, intermittent way. A lower comb conveys the vials while an upper st.st. comb serves as centering device.

The transfer combs are controlled by brushless motor configured for each size.

The high automation level makes the machine extremely user-friendly and flexible in its application. A "single index" or a "double index" machine configuration respectively allows a single/double vial transport system and a single/double stopper/alu cap chute with pick and place arm.



Machine configuration with upstream vial feeding table

Possibility to dose up to two different pharmaceutical products into the same vial (double dosing unit configuration): powder filling is carried out **by vacuum-pressure technology or, on request, by auger system, with dosages starting from 50 mg.**

Before and after filling, vials can be checked with **100% In-Process Control** of the filling weight with simultaneous automatic remote adjustment of the dosing disc chamber depth (**IPC**) and **purged with inert gas, as well.**

SMART PWD, according to dosing volume, product features and required production speed, can perform **an output speed up to 120 pcs/min.**

SMART PWD DOSING SOLUTIONS - AUGER TECHNOLOGY



SMART PWD IS THE KEY TO BREAK NEW GROUNDS IN POWDER PROCESSING.

AUGER TECHNOLOGY: THE PERFECT SOLUTION FOR ISOLATION TECHNOLOGY AND CIP/SIP SYSTEM INTEGRATION

Perfectly fit for integrating different dosing systems on the same dock, auger technology is a valid alternative to vacuum pressure filling system. Its concept as well as the compact and solid design, guarantee reliable application under cRABS or Isolation technology. CIP/SIP system integration contributes to keep a minimum particle generation level.

Auger dosing technology main features:

- The product is supplied directly into the hopper via dedicated feeder.
- The stirrer, driven by servomotor, conveys the powder close to the dosing auger working area.
- The auger, driven by servomotor, doses the product directly into the container.
- A lifting device holds up the container during filling process.
- Possible integration of a CIP/SIP unit for a perfect sterilization of all the parts in contact with the product.

- AUGER, STIRRER AND DOSING NOZZLE ARE DESIGNED IN FUNCTION OF THE PRODUCT CHARACTERISTICS, FILLING VOLUMES AND PRODUCTION SPEED REQUIREMENTS AND BY CONTAINER MOUTH DIAMETERS AS WELL.
- RAPID CONNECTION FOR ALL THE PARTS IN CONTACT WITH THE PRODUCT.
- MINIMAL PRODUCT RESIDUAL INSIDE THE HOPPER

HIGH FILL ACCURACY IS ACHIEVED WITH BOTH PRINCIPLES: DEPENDING MOSTLY ON POWDER TYPE AND DOSING VOLUME, BOTH VACUUM PRESSURE AND AUGER SYSTEMS CAN NORMALLY GUARANTEE THE ACCURACY REQUESTED BY THE AUTHORITY.



SMART PWD CHECK WEIGHING SYSTEM



Self-adjustment system of dosing chamber depth allows automatic correction of powder delivery in case of incorrect dosage

In presence **a vacuum pressure dosing** technology, a self-adjusting system of dosing chamber depth is available in case of 100% IPC system and motor driven chamber adjusting device. Aim of this self-adjusting program is to free the operator from carrying out weight corrections. The system provides for the automatic change of the dosing chamber depth during the production, thereby correcting possible trends to weight variations.

The system carries out a “clever” correction in case the machine is set to run with multiple dosages. The computer checks the current dosing chamber volume and processes the required correction to both dosing discs, so as to avoid or reduce at the minimum any possible differences in the dosing chambers of both dosing discs.

Combined with 100% IPC this function permits to minimize product waste.



USER FRIENDLY HMI FOR PROCESS MONITORING

HMI friendly interface, based on GE iFIX platform, easily accessible location, complete with PC touch-screen and dedicated software developed according to the GAMP5 guidelines and 21 CFR part 11 compliance. Direct management of all various machine operations and direct access to maintenance information, such as:

- POWDER LOADING OPERATIONS
- CHECK WEIGHING SYSTEM CALIBRATION AND RECORDING
- ALARM DATA RECORDING
- PRODUCTION PARAMETERS SET-UP
- MACHINE FUNCTION CHECKS AND SETTINGS
- RECIPES STORAGE



100% IPC net weight sampling before dosing



100% IPC gross weight sampling after dosing

SMART PWD 100% IN PROCESS CHECK WEIGHING SYSTEM FOR HIGHLY PRECISE QUALITY AND PROCESS CONTROL.

THE FINE ART OF CHECK WEIGHING: ADVANCED 100% IN PROCESS CHECKWEIGHING

SMART PWD sophisticated 100% check-weighing system is designed to meet today's pharmaceutical production requirements.

SMART PWD can perform, during production process, the 100% check weighing of the whole total number of the produced vials, granting a speed up to 120 vpm (double index configuration). To this aim, one or two loading cells are placed before the powder dosing station to check the net weight and to store relevant data by PC Control System. Containers are directly left on scales from the intermittent motion of the transport system.

One or two additional loading cell/s (depending if single or double index configuration) is/are placed after the powder dosing station, for gross weight check and data storage by PC Control System.

In case of simultaneous filling of **two different pharmaceutical powders into the same vial**, an additional, intermediate net check-weighing is performed, between the two powder dosages. The overall stored data are then stored and can be printed out at batch end. The feed-back to the dosing system is included.



SMART PWD CLOSING STATION AND OUTFEED

VIALS ARE STOPPERED ACCORDING TO THE SETTINGS IN THE RECIPE. STOPPERING HEAD ADJUSTMENT BY SERVOMOTORS, WITHOUT TOOLS.





STOPPERING STATION FOR HIGHEST PRODUCTION PROTECTION

Stoppers are fed by a vibrating bowl and are picked up by a quick-release pick & place vacuum assisted arm and placed onto the vials' mouth.

The pick & place device is controlled by brushless motor, configured for each vial size.

The stoppering head is automatically height adjustable by means of servomotor. A dedicated stopper pre-feeding unit is installed inside the safety cabinet.

STOPPER CONFIRMATION PRESENCE & HEIGHT CHECK



INTEGRATED CAPPING AREA

A possible integrated capping station can be installed in a separate area. Capping positioning is carried out by a pick & place arm. During capping operation, the vial rotates against an idle roller thus granting a very low particles generation.

The operations are servo-driven by automatic adjustment from HMI. Caps pre-feeder is installed inside the safety cabinet.

LIQUID DOSING UNIT

An additional liquid filling unit, equivalent to conventional fillers, can be fit after the powder dosing station for media fill purposes. It is commonly set with 1 or 2 (in case of double index) coaxial peristaltic heads, driven by a stepping motor with dosage programs selectable by HMI. Dosage is included between 1 and 30 ml, with +/- 2% accuracy. Production: up to 60 ppm.

Vials are automatically rejected and conveyed onto a dedicated outfeed belt in case of:

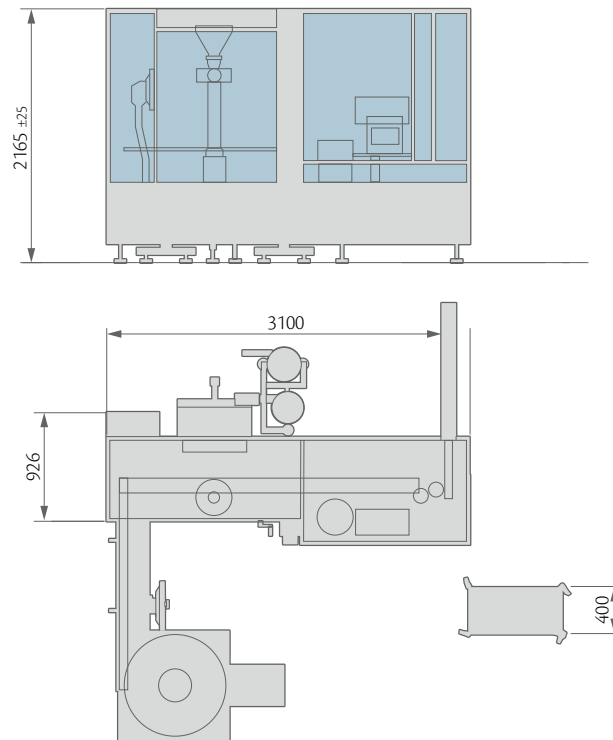
- Missing or displaced rubber stopper.
- Incorrect weight due to the first or second or third dosage (if present).



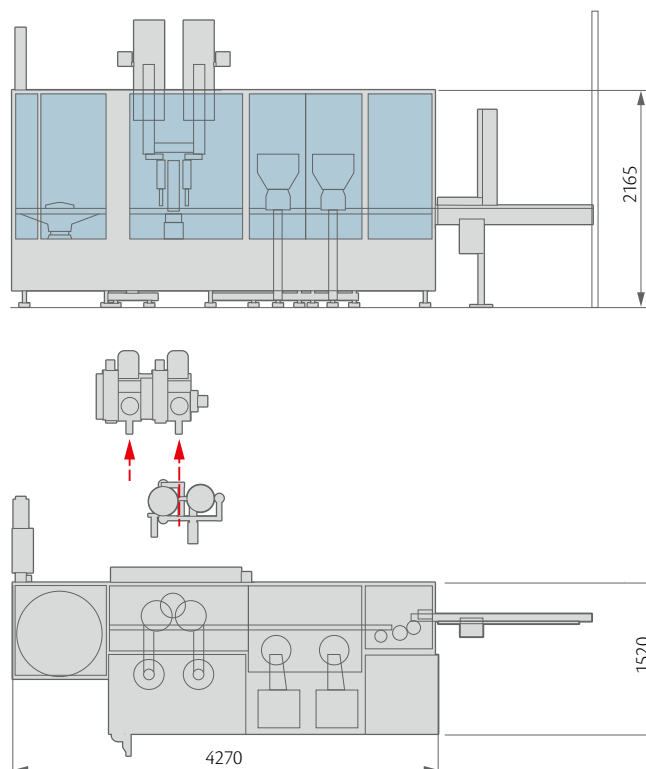
Vial rejection in case of missing stopper



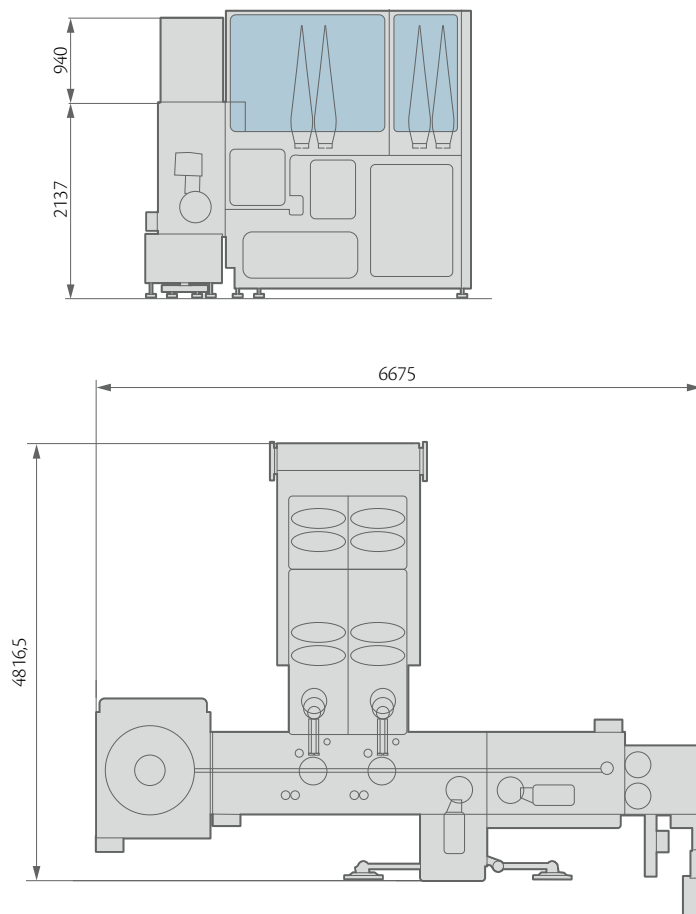
SMART PWD TECHNICAL DATA



Example of SMART PWD lay out configuration: vacuum pressure technology with 1 powder filling station



Example of SMART PWD lay out: vacuum pressure technology with 2 powders filling stations



Example of SMART PWD lay out: auger technology with 2 powders filling stations

SMART PWD Series		
	Min.	Max.
Vial diameter	22	52
Vial height	35	115
Stopper diameter	20	33
Stopper height	-	25
Filling volume	From 10 mg	
Output with 100% IPC *	Up to 150 vpm (double index) Up to 90 vpm (single index)	
Transport system	Intermittent motion	
Standard voltage	400 V, 50 Hz, 3ph + N + G	
Installed power	19 kW	

*According to filling volume, product type and dosing system.

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IMA S.p.A. - **LIFE division**
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