

DOSE DIVIDERS

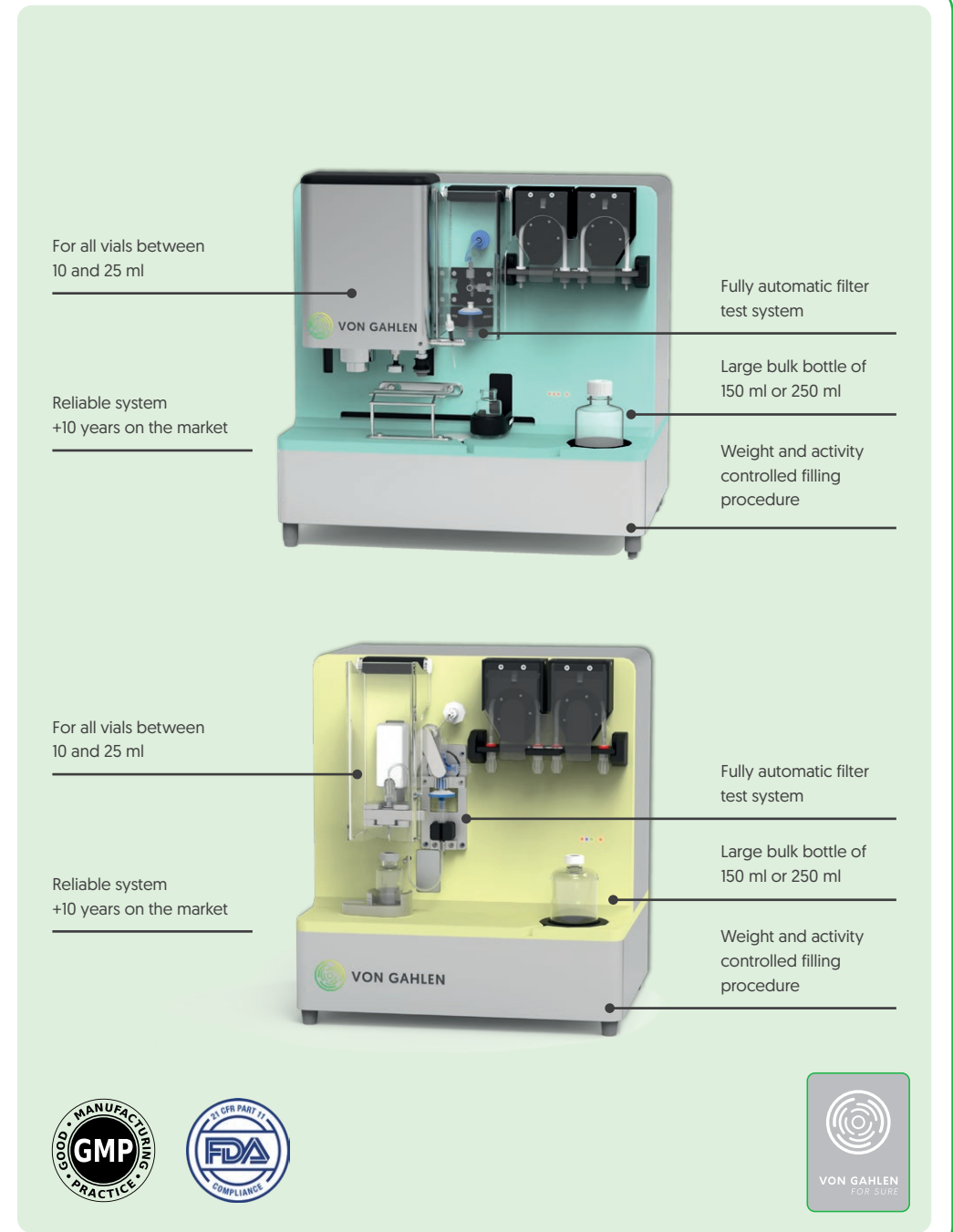
Our semi-automatic dose dividers are available in open and closed vial dispensing variants. Our dispensing units are designed according to GMP regulations and divide the bulk product into vials using either the pierced septum method or open vial filling. When placed inside our dispensing hot cell they provide a complete solution for aseptic manipulation and dispensing of radiopharmaceuticals into a patient dose.

The dispensing process includes batch production and filling of the pre-sterilized vials. These required vials are standard and sourced locally; the disposable set is specially designed for the dose divider and is available at Von Gahlen. This automated vial-filling process has a total cycle time of less than 55 seconds.

The dose dividers are remotely operated by tongs when there's activity inside the hot cell. When the hot cell is in "cold condition", the glove ports in the airtight acrylic door can be used. The filling procedure is fully automatic, but vial measurement, input, and output are done manually.

The package includes a complete solution with a dose divider, a calibrated ion chamber (various options and brands supported) with an automatic lift system, an industrial controller with a large screen, intuitive user software, and two label printers.

Variants	OVDD-SA-CAN	CVDD-SA-CAN
Filling method	open vial	pierced septum
Filling capacity	1 to 25 mL	1 to 25 mL
Cycle time (@5 mL)	55 s	55 s
Vial type acc. ISO 8362	R10 to R25	R10 to R25
Outside dimensions [mm] [W*D*H]	470*340*440	400*340*440
Floor space	420*270	350*270
Weight [Kg]	25	22



For all vials between 10 and 25 ml

Reliable system +10 years on the market

Fully automatic filter test system

Large bulk bottle of 150 ml or 250 ml

Weight and activity controlled filling procedure

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GMP PRACTICE

FDA COMPLIANCE 21 CFR PART 11

VON GAHLEN FOR SURE



STANDARD FEATURES

Radiation protection

- Internal Tungsten shields for enhanced life.
- Fully integrated dose measurement for our most commonly used Dose calibrators.

Sample & product handling

- Ease of operating using one or two ball tong manipulation units. (filling is a fully automated process).
- Glove ports in acrylic front door required for aseptic, cold preparation. (installing disposable cassette).
- Complete integration with the Von Gahlen Product Retrieval. Drawer system and the Von Gahlen Type-A transport container.

Air handling / distribution

- The construction for laminar downflow ensures a sterile. environment, designed in compliance with the current Good Manufacturing Practices (GMP) standards.
- Designed for laminar downflow (top to bottom) with an acrylic cover panel for air guidance.

Cleaning

- Housing made out of a combination of Corian and a high-grade 316L stainless steel with special micro-surface treatment.
- Exterior smooth surface finish for easy cleaning.
- Unit is compatible with hydrogen peroxide vapor decontamination, generator not included.

Sensors

- Activity accuracy: max 10% deviation of the dispensed activity relative to the requested activity.
- The weight of the product vial is measured during the filling cycle.
- Sensor for integrated FIT test.
- Barcode reader for vial recognition system.

System operation / control

- To operate the dispenser, a user-friendly, intuitive interface is provided.
- The software-guided dispensing is done based on input from the ion chamber and user data based on recipe management.
- Software is based on making a recipe, which is your product, and a batch that contains several types of vials (QC, drain, cleaning, test or productions vials).
- A pre-production record can be created remotely.
- The data of each batch is logged and stored in the database. Pre-batch reports, batch reports, and vial- & container labels can be printed or paperless.
- Audit Trail, in accordance with risk management principles, captures general system events as well as any activities relating to the acquisition, deletion, overwriting and changes to data for audit purposes.
- The high-level system components (dose divider, ion chamber, printers, etc.) are connected to a SCADA application's industrial controller.
- Vial- and container labels are fully customizable by authorized users.
- Implementation of software is conformed to SDLC (software development life cycle).
- Development and validation of software according to GAMP and is technically compliant with Eudralex V4 Annex 11 and 21 CFR Part 11.

Utilities

- Fully automatic in-line filter integrity test system.
- Two label printers: one label with the expected activity and volume for the vial (applied before filling) and the second for the measured activity and volume, to be applied after filling on the Type A container.
- Additional dilution, top-off, and cleaning cycles available.
- Cassette-based, double-packed, sterile disposable set; see separate product sheet.
- It is possible to perform multiple runs without waiting until the radiation has decayed.
- Switching between different products is easy; max time is 15 minutes without the risk of cross-contamination.

OPTIONAL FEATURES

- Autoclave integration (autoclave and validation not included).
- Tube cutter.
- Dilution bag holder.
- Target line connector.
- Varies vial racks stainless steel 316L / PEEK.
- Vial holders for various vials other than standard.
- Micro suction cup system for open center caps.
- Crimper for flip-off caps or normal caps.

