



VON GAHLEN

OPEN VIAL DOSE DIVIDER

The open vial dose divider automatic is an automatic vial dispensing system for safe and accurate dispensing inside a shielded hot cell. The dispensing process includes opening, filling, capping and crimping of the pre-sterilized vial. This automated process has a total cycle time of less than 55 seconds (dispensing 5 ml).

The OVDD-SA is remotely operated. The package includes the dose divider, a calibrated ion chamber with automatic lift system, an industrial PC with large screen and two label printers. Double packed sterile consumable sets are available.

 **Model VG-OVDD-SA**

KEY FEATURES

- Dispensing volume: 1-20 ml
- Uses standard 20 ml vials, but can be easily adapted for different vial sizes
- Cassette based, double packed, sterile disposable set
- Critical 'vial open' time is max 8 seconds, excluding dispensing time
- Activity accuracy: max 10% deviation of the dispensed activity relative to the requested activity
- Cycle time: ≤ 55 seconds, dispensing 5 ml
- Fully automatic in-line filter integrity test system
- Additional dilution and cleaning cycles available
- The weight of the product vial is measured during filling
- The product vial is capped and crimped
- Multiple runs possible without waiting for the activity to decay
- Switching between different products is easy, max time is 15 minutes without the risk of cross contamination

**FOR ALL VIALS BETWEEN
10 AND 25 ML**

HIGH PRECISION FILLING



**FULLY AUTOMATIC
FILTER TEST SYSTEM**

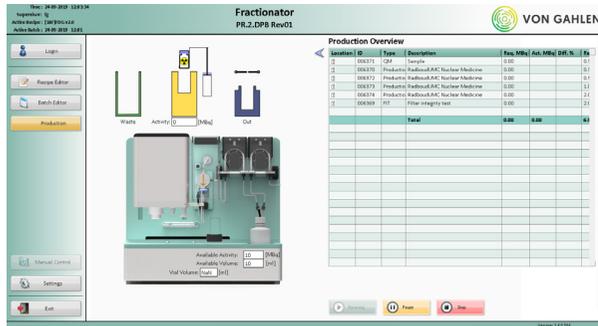
**LARGE BULK BOTTLE
OF 150 ML**

**WEIGHT
CONTROLLED
FILLING PROCEDURE**

YOUR GUARANTEE FOR QUALITY. FOR SURE.



**VON GAHLEN
FOR SURE**



TECHNICAL DATA

- Overall space required: ± 470*350*460 mm [W*D*H]
- Floor space: ± 420*280 mm [W*D]
- Height: ± 410 mm
- Weight: ± 20 kg

SOFTWARE

- To operate the dispenser a user friendly, intuitive interface is provided.
- The software guided dispensing is done based upon input from the ion chamber and user data based upon recipe management.
- A pre-production record can be created remotely. The data of each batch is logged and stored in the database. Batch reports and vial labels can be printed.
- The high level system components (dose divider, ion chamber, printers etc.) are controlled by an industrial PC running a Windows application.
- Vial- and container labels are fully customizable by authorized user.
- Implementation of software and firmware are conform SDLC (software development life cycle).
- Development and validation of software according to GAMP and are technically compliant with Eudralex V4 Annex 11 and 21 CFR Part 11.

DISPOSABLES / CONSUMABLES

- Standard disposable set based upon PE/silicone material
- Other disposable sets available upon request

QUALITY CONTROL

- ETO sterilized in accordance with ISO11135
- Sterility is tested and approved according to 21 CFR 212 media fill test and ISO 13408-1 (2015)
- ETO residual tested (1 PPM)
- LAL-Endotoxins
- Shelf-life 5 years (determined according to ISO 11607)
- Leachables and Extractables tested and approved according to ISO 10993-18
- Components have no origins that could result in contamination by Transmissible Spongiform Encephalitis (TSE), Bovine spongiforme encefalopathie (BSE) or melamine
- Every batch will be delivered with an Certificate Of Analysis (COA) which contains at least:
 - Lot or batch number
 - Quality Release Testing Assay (Sterility, Bacterial Endotoxin test)
 - Product Expiration Date
 - Product Release Date including quality Assurance Approval



MORE INFO?
Please contact
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Or visit
www.vongahlen.com

