VON GAHLEN

OPEN VIAL DOSE DIVIDER FULLY AUTOMATIC

The open vial dose divider fully automatic is a fully 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 can fill 50 vials per hour (based on 3 ml per vial) including fully automatic bulk formulation.
The OVDD-FA is remotely operated. The package includes the dose divider, pick and place unit, 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-FA

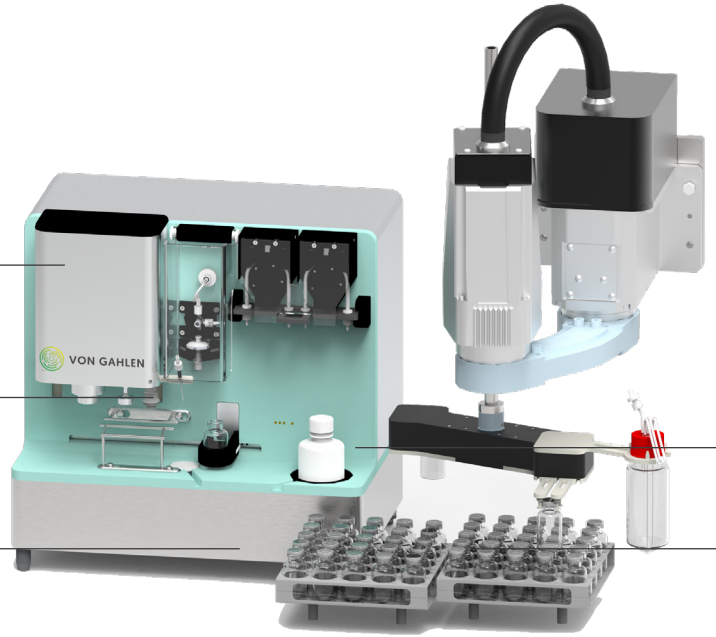
KEY FEATURES

- 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 without waiting untill the radiation has decayed
- Switching between different products without the risk of cross contamination
- Manual back-up using ball tong system

FULLY AUTOMATIC,
FASTEST SYSTEM
ON THE MARKET

FOR ALL VIALS
BETWEEN
10 AND 25 ML

HIGH PRECISION
FILLING



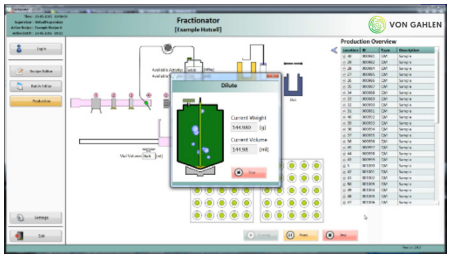
LARGE BULK
BOTTLE
OF 150 ML

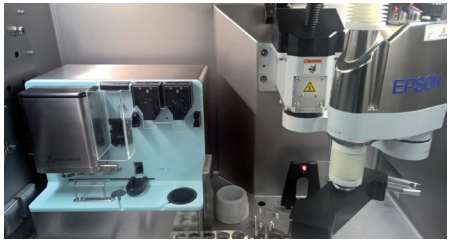
REMOTELY
OPERATED

YOUR GUARANTEE FOR QUALITY. FOR SURE.

VON GAHLEN
FOR SURE

VON GAHLEN





TECHNICAL DATA

- Overall space required: ± 1030*720*790 mm (W*D*H)
- Floor space: ± 420*280 mm (W*D)
- Height: ± 410 mm
- Weight: ± 40 kg

SOFTWARE

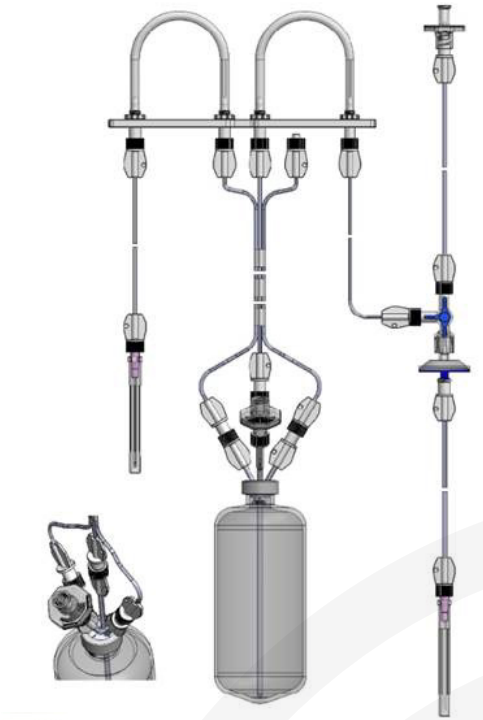
- To operate the dispenser a user friendly, intuitive interface is provided.
- The software guided dispensing is done based upon input from the ion chamber and user data based upon recipe management.
- A pre-production record can be created remotely. The data of each batch is logged and stored in the 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 Transmittable 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?
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TÜV NEDERLAND ISO 9001