Process Vessels

Pharma Vessels and Fermenters

GEA Process Engineering

GEA Diessel

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Inspired design – trusted quality – ultimate performance

The value of quality can never be overestimated. Ultimately, it is quality that drives efficiency, security of outcome, whole-life costs and productivity throughout industry. GEA Diessel is the worldwide specialist in the manufacture of vessels for the pharmaceutical and biotech industries. At GEA Diessel, quality is never a compromise.

Where inspiration meets technology

Pharma Vessels and Fermenters

Where quality really matters

The demands of microbial and cell fermentation, and the handling of high-value pharmaceutical products, require the highest possible quality from the vessels and fermenters used. The key to efficiency and performance is manufacturing excellence: high quality materials, precise engineering, meticulous quality control; and inspired design: sterile operation, no dead areas, integrated CIP/SIP, high-quality individual components and, where needed, a clear and easy-to-use control and visualisation system.

GEA Diessel is a single source for the supply of vessels and fermenters to meet the needs of any pharmaceutical, microbial or cell fermentation process. The company has the expertise and industry knowledge to help customers test processes and make the right choice of equipment to ensure security of outcome and the fastest time to market.

All vessels can be supplied as stand-alone equipment or as automated process units delivered as fully-functional modules installed on-site that include: agitators, homogenisers, metering and regulating technology, control units, valves and pipe connections. Options for hazardous environments are also available.

High value inside: high quality outside

Fermenter range and technical specifications

- Standard unit sizes: 10 to 15,000 litres
- Bespoke systems designed to each customer's requirements
- H/D 3:1, 2:1, 5:1
- Internal surface Ra ≤ 0.5 µm (≤ 20 µinch) electro-polished
- Pressure: -1/+3 bar; -1/+6 depending on customer's requirements
- Temperature: -20 °C /200 °C (SIP up to 130 °C)
- Cleaning options: CIP, SIP
- Single, double and triple-wall design – heated, insulated

Pharma Vessels range and technical specifications

- Preparation vessels and storage tanks
- Stationary or mobile options in vertical or horizontal orientation
- Single, double and triple-wall design – heated, insulated
- Half-pipe/double jacket and spiral
- Fully insulated and clad
- Capacity: 2 to 20,000 litres
- Operating pressures: -1 to 10 bar
- Operating temperature: up to 200 °C

Quality credentials

- cGMP/FDA
- Manufactured as per PED (Pressure Equipment Directive)
- ASME U-Stamp
- China Manufacture License (SELO)
- Quality plan and materials tracing
- Own non-destructive testing
- Weld seam documentation
- Qualification (IQ/OQ)
- Quality Management System according to DIN EN ISO 9001

Welding and grinding

The welding and grinding techniques used in the manufacture of pharmaceutical vessels and fermenters largely define the quality. The strength of seams and the quality of the polished surfaces ensure long service and operational efficiency.

GEA Diessel manufactures its vessels using only high-alloy stainless steels. These materials require the most exacting welding and grinding techniques to ensure the integrity, long life and reliability of the vessels.

TIG welding (Tungsten Inert Gas) is preferred as it offers the best guarantee of perfect welded seams, however MAG (Metal Active Gas) and orbital welding are also suitable in some applications. GEA Diessel welders are experienced in all techniques and always achieve thorough penetration, a high quality finish and reproducible quality. All welds are checked using the latest techniques to provide continuous monitoring of results.

Surface quality is achieved using dry grinding techniques with specially designed vertical grinding and sanding equipment in the hands of expert craftsmen. The result is a final product of the highest surface quality. Surfaces may also be pickled, passivated or electropolished if required.

Technical information

- Materials in regular use: Stainless Steel types: 1.4404, 1.4435, 1.4541, 1.4571, 1.4539, 1.4547 (SMO), 2.4605 (Alloy), 2.4610 (Alloy)
- Defined surface finish (dry grinding) up to Ra ≤ 0.2 µm
- Optional: pickled and passivated or electropolished
- Delta ferrite content < 0.5 %

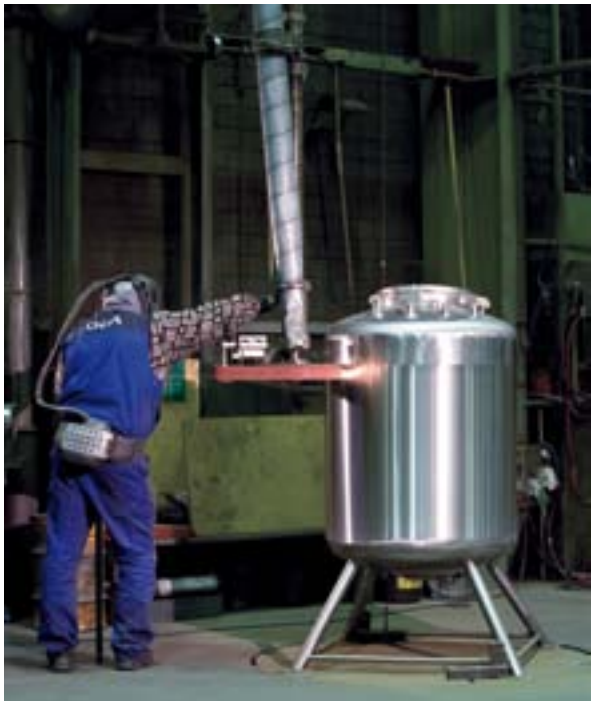
Cleaning

The cleaning characteristics of pharma vessels and fermenters are key, right from the start of the design process. It is essential to eliminate dead-leg areas and ensure that Clean-in-Place (CIP) and Sterilise-in-Place (SIP) systems are effective.

GEA Diessel uses the latest computer-aided simulation of theoretical spray patterns during the design phase to ensure cleaning in accordance with every customer's requirements. Cleaning systems are designed to minimise the use of cleaning media, thereby reducing running costs. This cleaning capability is then verified in practice, using a Riboflavin test, for every vessel supplied.

The cleaning of the exterior of the vessel is important too, and all GEA Diessel vessels are designed with appearance and practicality in mind. Exterior features, designed for easy cleaning and to ensure a safe working environment for operators, include:

- Round edges and corners
- Homogeneous surface finish (with certificate if required)
- No indentations or pits
- Gap-free components and accessories



Mixing, heating and cooling

Temperature control and agitation during the process are key to achieving a successful and repeatable outcome. GEA Diessel ensures that the temperature of products within fermenters and vessels can be controlled within narrow limits (± 0.5 °C) to achieve the highest growth and product formation rates and avoid product variation during production.

This high degree of temperature control throughout the heating, production and cooling processes, and product homogeneity is achieved using the latest heat exchanger technology and careful agitation. Precise instrumentation measures all the key parameters of pH, pO_2, temperature, agitator speed and weight, throughout processing.

Quality control and testing

Throughout the manufacturing process all vessels and fermenters are subject to stringent quality checks. An overall test forms part of the FAT (Factory Acceptance Tests) procedures and the relevant documentation forms part of the FAT protocols. Customer-specific factory acceptance tests (FAT) include:

- Riboflavin test
- Heating/cooling test
- Surface roughness measurement
- Delta ferrite determination
- Electrical testing as per VDE (e.g. agitator test, control cabinet test etc.)

Material traceability of vessel parts and components

Our quality management system ensures the full traceability of all materials used including the provision of certificates.

parenterals · fermentation / media supply · syrup and suspensions · blood plasma · highly purified media · process vessels · special liquids

Process Vessels

Pharma Vessels and Fermenters

GEA Diessel specialises in planning, construction and qualification of sterile process plants for liquids in pharmaceutical and biotechnology industries. Our process systems are operational within the area of parenterals, fermentation, feed media, blood plasma and special liquids as well as clean utilities.

GEA Diessel has 80 years of expertise and know-how in plant and equipment technology and holds a decisive position in development of modern process technology today.

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GEA Diessel GmbH

Steven 1 · 31135 Hildesheim · Germany
Phone +49 5121 742-0 · Fax +49 5121 742-153
info.geadiessel.de@geagroup.com · www.diessel.com

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