

Try Excellence in Biotechnology

Westfalia Separator CareTechnology



What You Purchase is a Separator ...

.. what you get is more than 113 years of
experience in centrifuge construction.

Aseptic process management, optimum
cleaning capability, closed product hand-
ling, gentle product treatment, reliable
compliance with GMP requirements, effi-
cient recovery of active ingredients and
reliable scale-up – the requirements of
biotechnology are demanding.

With separators designed specifically
for biotechnology, Westfalia Separator
CareTechnology stands for reliable com-
pliance with these requirements.



Pioneers from the Beginning

Westfalia Separator built the first centrifuge in 1893 in Oelde in Westphalia. Since that time, the company has been at the forefront of shaping progress in centrifugal separation technology. Today, it is a key technology in the recovery of pharmaceutical active ingredients with considerable potential for optimising production processes and products.

The separators, decanters and process lines from Westfalia Separator have a proven track record throughout the world in high-performance companies of all types and sizes and under a wide range of conditions. Experience and knowledge gained in these fields support the optimisation of separating systems and processes as well as the development of fundamentally new concepts, e.g. in drive systems, design and functionality.

Proven innovative strength

A striking aspect of the success of the company in biotechnology is the speed with which new developments are translated into marketable processes and systems which take account of the complex requirements of biotechnology right down to the smallest detail. This is based on the decades of experience in the design and production of separators for biotechnology, the use of new research

findings as well as the implementation of the latest design and production methods. For instance, Westfalia Separator has developed numerous forward-looking improvements of separating processes and has ensured that they are marketable throughout the world by means of first-class engineering. Overall, the company can now handle more than 2500 applications.

Under the designation Westfalia Separator CareTechnology, Westfalia Separator uses this potential in pharmaceutical biotechnology.

Customers are benefiting particularly in this dynamically expanding market sector from the design implementation of stringent technical standards, hygienic design and gentle product treatment right through to the reliable compliance with all GMP requirements and a reliable scale-up.

Innovations – Engineered with Care

In biotechnology, the separators from Westfalia Separator are used for processing mammalian cell cultures, recovering pharmaceutical proteins and vaccines, producing hormones such as insulin, fractionating human blood plasma and also for recovering many other pharmaceutical active ingredients.

Improvements and new developments with Westfalia Separator **CareTechnology** focus entirely on the safety of biotechnology processes and the efficiency of recovering the active ingredients.

In order to comply with the stringent safety requirements applicable for production processes in biotechnology, centrifuges from Westfalia Separator incorporate a wide range of special features which stand for high yields of valuable substances, gentle product treatment and optimum CIP and SIP capability.

The Westfalia Separator HydroStop system

ensures better utilisation of the resources used, and thus guarantees a high yield of valuable substances. The system dramatically reduces ejection times, thus minimising product losses. It permits partial ejections in 30-second cycles with precisely reproducible discharge quantities. With total ejections during cleaning-in-place, it also ensures very strong flow turbulence in the bowl, so that solids are reliably flushed out of the separator.

The full-sterilisation principle

With regard to sterilisation, Westfalia Separator **CareTechnology** exclusively uses the full-sterilisation concept in which the entire installation including the separator is sterilised. Compared with other procedures, in which only certain areas are covered by this procedure, the risk of recontamination can be reliably excluded. This concept has been validated by GBF in accordance with FDA requirements.

The hydrohermetic feed system

is gentle on sensitive products. This patented feed system reduces shearing forces when product enters the separator, and thus retains the vitality of fragile cells. Unlike completely hermetic machines, there are no seals which are subject to wear-and-tear in the chamber which comes into contact with the product, and product contamination from this source is thus avoided.





Viscosity-controlled nozzle-type separators (VISCON®)

also improve the treatment of starter cultures and the recovery of hormones and pharmaceutical proteins. Even in conjunction with fluctuating feed conditions, Westfalia Separator VISCON® nozzles automatically ensure a constant discharge concentration.

By placing the VISCON® nozzles on the bowl head instead of the periphery, the pressure on the separated cells is also much lower.

Hygienic design

With a welding method developed by Westfalia Separator, the spacers can be welded on to the discs without any gaps. The result: dead legs in which bacteria can collect and pose a risk to product purity are reliably prevented. A further benefit is the fact that seals and seal grooves do not feature any dead legs, and maximum surface qualities ensure optimum cleaning capability of the separators.

Tested safety

The function entity comprising the separator, control and sterile package which is configured to meet the user's specific requirements is assembled on a base frame, automated and subjected to a function test (FAT) before being delivered to the customer. The latter also comprises a steam sterilisation test for each package unit on up to six measuring points. On the premises of the user, it is only necessary to connect the lines for product and operating media.

GMP-compliant documentation

Westfalia Separator **Care**Technology of course includes the complete documentation in accordance with current GMP requirements. For this purpose, Westfalia Separator set up a separate GMP group a few years ago, and this group comprises all relevant departments. The team meets at frequent intervals to work new market developments into the documents and accordingly implement new requirements. The documents and staff are consequently always kept up to date which means safety for the user.

Reliability from the Test Tube Right Through to Marketability

As far as product development in biotechnology is concerned, Westfalia Separator assists you as an experienced partner when the need is to convert your lead as a pioneer and developer of a new product into permanent market success. This involves the reliable route from the initial laboratory tests and the pilot installation right through to the full-scale installation.

Westfalia Separator guarantees a reliable scale-up based on decades of experience, computer-aided simulations and a comprehensive range of separators for biotechnology.

Up to ten years development time and investments running into ten digits, e.g. in the production of medical products, again show that methods such as “trial and error”, “test, study and test again” constitute an unforeseeable risk on the route from the initial test tube through to the marketable industry batch.

In this context, Westfalia Separator **CareTechnology** involves reliably transferring results achieved with the new active ingredients in the laboratory scale to full-scale production. A wide range of

separators for biotechnology with different production capacities and designs is available for this purpose. From the smallest nozzle-type separator with VISCON® technology right through to the largest steam-sterilisable centrifuge in the world, namely CSE 170, Westfalia Separator offers a comprehensive range of separators to enable all customer needs and capacity ranges to be satisfied.

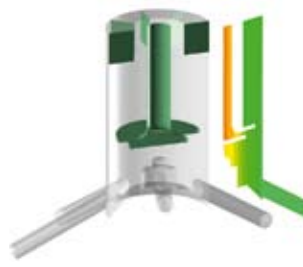
With regard to designing separators for pharmaceutical biotechnology, Westfalia Separator relies not only on its know-how established over decades. By using computer-aided CFD calculations, the conditions in the centrifuge are simulated on the basis of the relevant product and machine parameters. In this way, the



Numeric flow simulation CFD (Computational Fluid Dynamics) can be used, for example, to examine the flow characteristics of liquids and liquids with particles. Particularly with regard to the scale-up of separators in biotechnology, CFD simulations have proven to be a useful additional tool whose results are utilised for optimisation of the centrifuges during the construction phase.



CSA 8



CSC 15



CSE 80



CSE 170

separators are provided with optimum design in the design phase for the requirements of pharmaceutical biotechnology, irrespective of the product capacity for which they are designed. The results of pilot trials can thus be reliably transferred to the industrial scale.

Customers benefit in two ways from this scale-up safety. They can reliably and quickly launch their product on the market by generating basic data, and by evaluating and simulating the product and process parameters. In this way, they take advantage of all benefits provided by a separator in the downstream process.

CFD calculations split the flow area into numerous control volumes. In this process, conservation equations are formulated for mass, momentum and energy. The solutions derived from these systems of equations can then describe the complete flow field. Here for instance, the relative pressure in the inlet area is illustrated.

- Beverage Technology
- Dairy Technology
- Oils and Fats Processing
- Chemicals, Pharmaceuticals and Biotechnology
- Oils and Fats Recovery
- Starch Technology and Industrial Biotechnology
- Environmental Technology
- Marine
- Energy
- Oilfield
- Industry
- Engineering
- Second Hand Machinery
- Service

The information contained in this brochure merely serves as a non-binding description of our products and is without guarantee.

Binding information, in particular relating to capacity data and suitability for specific applications, can only be provided within the framework of concrete inquiries.

Printed on chlorine-free bleached paper
www.papp.cc

9997-1262-000/0506 EN
Printed in Germany
Subject to modification

**Westfalia Separator
Industry GmbH**
Werner-Habig-Straße 1
59302 Oelde (Germany)

Phone +49 2522 77-0
Fax +49 2522 77-2828
industry@gea-westfalia.de
www.westfalia-separator.com