



Cell culture media and solutions

Miltenyi Bioprocess provides custom-made sterile, pyrogen-free buffers, rinsing solutions, serum- or protein-free cell culture media. Formulation and production is performed under GMP conditions in our ISO 9001-certified facility in Teterow, Germany. All manufacturing processes and clean rooms are qualified and validated to ensure consistency and suitability. Starting with WFI monitoring, all chemicals used to manufacture liquids are of high purity and conform to the published quality standards.

Prior to product release, numerous quality controls are performed:

- sterility
- bioburden
- endotoxin
- solubility
- pH / osmolarity
- particle size
- key elements
- growth promotion parameters for cell culture media and biological buffers

Miltenyi Bioprocess offers single batch capacity in four different tank groups up to 5,000 L. Four tank groups are in place at Miltenyi Bioprocess:

- 2×2,000 L vessel connected to the filling line of non-PCV infusion bags
- 1×600 L vessel BioProcess containers
- 3×2,000 L vessel connected to the in-house distribution system
- 1×5,000 L vessel connected to the in-house distribution system
- 1×600 L vessel stand-alone stirred tank
- 1×300 L vessel stand-alone stirred tank

The equipment is serviced with CIP and SIP systems to prevent bioburden and endotoxin contamination. The liquid products are membrane-sterilized and aseptically dispensed into final containers (e.g. BioProcess container) or 0.22 µm-fil-trated and filled into non-PVC bags followed by a steam sterilization process. The filling processes are performed in a class 100 area. Filter integrity tests are performed before and after filtration using a pressure diffusion method.

Production, documentation, packing, storage, shipping and support systems are geared to the respective product profiles.

All work at Miltenyi Bioprocess is done according to international guidelines of Good Development Practices (GDP) and Good Manufacturing Practices (GMP).



Miltenyi Bioprocess

a division of Miltenyi Biotec

For additional information please contact:

Miltenyi Biotec GmbH
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany
Phone +49 2204 8306-0
Fax +49 2204 85197
bioprocess@miltenyibiotec.de

For US and Canadian customers:

Miltenyi Biotec Inc.
12740 Earhart Ave
Auburn, CA 95602
USA
Phone 800 367 6227 / 530 888 8871
Fax 530 745 2806
bioprocess@miltenyibiotec.com

www.miltenyibiotec.com