



Miltenyi Biotec

MACS® GMP Recombinant Human TNF-α

Order no. 170-076-103

Contents

1. Description
2. Applications
3. Warnings and precautions
4. Instructions for use
 - 4.1 Reconstitution
 - 4.2 Dilution
5. References
6. Appendix: Glossary of symbols

1. Description

Components	25 µg MACS® GMP Recombinant Human TNF-α.
Biological activity	The specific activity* is at least 2×10^7 I.U./mg. The biological activity of the specific lot is indicated on the Certificate of Analysis.
Molecular mass	17.35 kDa, determined by mass spectrometry. This corresponds to the mature form of human TNF-α (157 amino acids).
Identity	Confirmed by ESI-MS and isoelectric focusing.
Source	<i>E. coli</i> .
Statement of origin	No animal- or human-derived components were used for manufacture of this product.
Purity	≥97% as determined by chip electrophoresis.
Endotoxin content	<5 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Residual host cell DNA content	<2.5 ng DNA/vial as determined by quantitative PCR specific for <i>E. coli</i> genomic DNA.
Product format	Lyophilized without carrier protein or preservatives.
Sterility	Sterility of the bottled product is tested according to Ph. Eur.
Transport	At 2–8 °C.
Storage	Store lyophilized MACS GMP Recombinant Human TNF-α at –20 °C or lower directly upon arrival. Avoid repeated freeze-thaw cycles. The use-by date is indicated on the vial label.

* The specific activity is determined by cytotoxicity assay using L929 cells provided by the German Collection of Microorganisms and Cell Cultures (DSMZ) in the presence of 1 µg/mL actinomycin D according to Baarsch *et al.*¹ The cytotoxicity assay was calibrated with the international standard for human TNF-α (NIBSC code 88/786) provided by the National Institute for Biological Standards and Control.

Quality statement

MACS GMP Recombinant Human TNF-α may be used for research or *ex vivo* cell culture processing.

MACS GMP Recombinant Human TNF-α is manufactured and tested under a certified ISO 9001:2000 quality system and in compliance with relevant GMP guidelines. It is designed following the recommendations of USP <1043> on ancillary materials.

2. Applications

- MACS GMP Recombinant Human TNF-α can be used for a variety of *ex vivo* cell culture applications.

3. Warnings and precautions

- ▲ The instructions for use must be followed.
- ▲ For research or *ex vivo* cell culture processing.
- ▲ Not intended for human *in vivo* applications.
- ▲ Do not inject or infuse the product directly into a patient. Not for parenteral application.
- ▲ When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- ▲ For single use only. Do not re-use.
- ▲ Use undamaged and sealed vials only.
- ▲ Do not use after the use-by date indicated on the vial label.

4. Instructions for use

4.1 Reconstitution

▲ As the product contains no microbiological preservatives, the reconstituted product should be used directly. If not used directly, the user is responsible for storage time and conditions.

4.1.1 Reagent and instrument requirements

- Sterile syringe and needle.
- Sterile water for injection (WFI).

4.1.2 Protocol

- ▲ Work under sterile conditions.
- 1. Thaw the vial at room temperature. Disinfect surface of the vial before use.
- 2. It is recommended to reconstitute the lyophilized cytokine with 1 mL of sterile water for injection (WFI).
- 3. Use an appropriate sterile syringe and sterile needle to add 1 mL of sterile WFI to the lyophilized cytokine.
- 4. Remove the cap of the vial and disinfect the surface of the rubber plug.

5. Fill the syringe with 1 mL of sterile WFI. Puncture the rubber plug using the needle and carefully add the water from the syringe along the side wall of the vial. Avoid foam formation. Mix content thoroughly by carefully swaying the vial until all visible components are dissolved. This usually takes less than one minute. Do not shake or vortex.
6. Remove the reconstituted cytokine from the vial using a sterile syringe and a sterile needle.

4.2 Dilution

▲ For dilution with PBS or base medium a carrier protein should be included, which may have stabilizing effects.

▲ Dilutions should be prepared aseptically with either 0.5–1% recombinant human albumin or with 1–10% human autologous serum (HAS).

5. References

1. Baarsch, M. J. *et al.* (1991) Detection of tumor necrosis factor alpha from porcine alveolar macrophages using an L929 fibroblast bioassay. *J. Immunol. Methods* 140: 15–22.

6. Appendix: Glossary of symbols



Order number



Part number



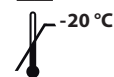
Batch code



Manufacturer



Use by



Upper limit of temperature



Caution, consult accompanying documents



Do not reuse



Not for *in vivo* applications in humans

All protocols and data sheets are available at www.miltenyibiotec.com.

Warranty

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