Miltenyi Biotec

MACS® GMP Rapamycin

Order no. 170-076-308

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1. Description

Components	1 vial containing 180 nmol MACS® GMP Rapamycin.
Product format	MACS GMP Rapamycin is supplied in 1 mL DMSO.
Endotoxin content	≤2 EU/mL as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Identity	Confirmed by mass spectrometry.
Purity	≥95% as determined by HPLC.
Sterility	0.2 µm filtered.
Transport	At room temperature (+15 °C to +30 °C [+59 °F to +86 °F])
Storage	Store at +2 °C to +8 °C (+36 °F to +46 °F) directly upon arrival.
Shelf life	The use-by date is indicated on the vial label.

Disclaimer

MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative.

Quality statement

MACS GMP Products are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

The declaration of animal- or human-derived materials is given on the Certificate of Origin.

Background information

Regulatory T (Treg) cells have been described to be hypoproliferative in reponse to polyclonal stimulation and interleukin 2 (IL-2) *in vitro*. The MACS GMP Rapamycin has been developed to selectively expand Treg cells and to maintain FoxP3 expression.[1]

2. Applications

- Expansion of human Treg cells after isolation from human blood, peripheral blood mononuclear cells (PBMCs), or cord blood.
- Expansion of $CD25^+$ cells enriched with the CliniMACS® CD25 Reagent.

3. Warnings and precautions

- ▲ The instructions for use must be followed.
- ▲ Do not inject or infuse the product directly into humans. Not for human 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 reuse.
- ▲ Use undamaged and sealed vials only.
- ▲ Do not use after the use-by date indicated on the vial label.

4. Instructions for use

The content of MACS GMP Rapamycin is sufficient to result in a 100 nM ready-to-use Treg expansion medium in combination with TexMACS™ GMP Medium.

4.1 Reagent and instrument requirements

- Sterile syringe and needle.
- (Optional) TexMACS GMP Medium (# 170-076-306)

4.2 Protocol

- ▲ Work under sterile conditions.

1. MACS GMP Rapamycin is supplied in 1 mL DMSO. DMSO congeals at temperatures below 18 °C. If necessary, warm opalescent and congealed DMSO at a temperature between 18 °C and 30 °C until it becomes clear and liquid again.
2. Disinfect surface of the vial before use.

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3. Use an appropriate sterile syringe and sterile needle.
4. Remove the cap of the vial and disinfect the surface of the rubber plug.
5. Fill the syringe with 1 mL of MACS GMP Rapamycin.
6. Fill the content into 1 bag of TexMACS GMP Medium (2000 mL, flexible bag).
7. Mix content thoroughly by carefully moving the bag.

For protocols for the expansion of Treg cells please refer to **www.miltenyibiotec.com** or contact your local sales representative.

5. Reference

1. Battaglia, M. *et al.* (2005) Rapamycin selectively expands $CD4^+CD25^+FoxP3^+$ regulatory T cells. Blood 105: 4743–4748.

6. Glossary of symbols

	Manufacturer		Use-by date
REF	Order number		Phone
P/N	Part number		Fax
LOT	Batch code		E-mail
	Consult instruction for use		Website
	Do not use if package is damaged.		

This data sheet and corresponding information as well as special protocols can be found under **www.miltenyibiotec.com/170-076-308**.

Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. Miltenyi Biotec B.V. & Co. KG makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the technical specifications of the products. Miltenyi Biotec B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

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