Miltenyi Biotec

MACS® GMP Vectofusin®-1

Order no. 170-076-165

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1. Description

Components	1 mg MACS GMP Vectofusin®-1: polypeptide
Capacity	Up to 100 mL of transduction volume.
Product format	Lyophilized synthetic peptide as trifluoro-acetate salt, containing stabilizer.
Identity	Confirmed by HPLC/ mass spectometry (ESI-MS).
Purity	Purity ≥95% as determined by RP-HPLC.
Sterility	Sterility of the bottled product is tested according to Ph. Eur.
Transport	At +2 °C to +8 °C (+36 °F to +46 °F)
Storage	Store lyophilized MACS GMP Vectofusin-1 at –20 °C (–4 °F) or lower directly upon arrival. Avoid repeated freeze-thaw cycles.
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.

2. Applications

- MACS GMP Vectofusin-1 can be used for a variety of applications, for example, enhancement of viral transduction of suspension cells. It can be also used in combination with automated processes on the CliniMACS Prodigy® instrument, for example to modify T cells with retroviral vector constructs.

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 the reagent only if the vial is undamaged and sealed.
- 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.
- Work under sterile conditions.

4.1.1 Reagent and instrument requirements

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

4.1.2 Protocol

1. Thaw the vial at room temperature. Disinfect surface of the vial before use.
2. It is recommended to reconstitute the lyophilized MACS GMP Vectofusin-1 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 peptide.
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.

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Mix content thoroughly by carefully swaying the vial until all visible components are dissolved.

6. Remove the reconstituted MACS GMP Vectofusin-1 from the vial using a sterile syringe and a sterile needle.

4.2 Cell transduction

▲ One vial of MACS GMP Vectofusin-1 is sufficient to transduce target cells in a final culture volume of up to 100 mL.

▲ Before transduction, determine the cell number to be able to calculate the volume of viral vector required to reach the desired multiplicity of infection (MOI).

1. Prepare cells in the desired format and cell concentration.

▲ **Note**: The required final concentration of MACS GMP Vectofusin-1 for transduction is 10 µg/mL in the total culture volume.

2. Prepare MACS GMP Vectofusin-1 as described in section 4.1.

▲ **Note**: The required final concentration of MACS GMP Vectofusin-1 for transduction is 10 µg/mL in the total culture volume.

▲ The volume should be low enough to allow the addition of the viral vector supernatant, MACS GMP Vectofusin-1, and plain culture medium without serum or lipids. For calculation examples refer to "Preparation examples of MACS GMP Vectofusin-1 transduction mixtures" below.

3. Dilute viral vector/viral supernatant and MACS GMP Vectofusin-1 separately by adding plain culture medium. Both diluted solutions shall have identical final volumes.

4. Mix diluted viral vector/viral supernatant and diluted MACS GMP Vectofusin-1 solutions by vortexing or rocking.

5. Add the mixture of viral vector/viral supernatant and MACS GMP Vectofusin-1 to the cell suspension and pipette up and down. For automated procedures on the CliniMACS Prodigy, fill the mixture into a suitable bag and attach to the CliniMACS Prodigy tubing set by sterile welding.

▲ **Note**: Duration between mixing the viral vector and MACS GMP Vectofusin-1 and addition of the mixture to the target cells should be 5–30 minutes.

6. Cultivate cells at +37 °C (+99 °F).

7. (Optional) To reach a higher transduction performance, centrifuge cell samples at 400×g for 1–2 hours at +32 °C (+90 °F) followed by static incubation at +37 °C (+99 °F).

8. Wash cells once 6–24 hours after transduction with transduction medium. Refill to desired culture volume and cultivate the cells at +37 °C (+99 °F).

Preparation examples of MACS GMP Vectofusin-1 transduction mixtures

MACS GMP Vectofusin-1 can be used with both purified viral vector and cell culture supernatants. Examples for preparing transduction solutions with different volumes of viral vector or viral supernatant and in different cell culture formats are given below.

	96 well (µL)	24 well (µL)	CliniMACS Prodigy (mL)
Retroviral supernatant	20	–	20
Purifed vector	–	5	–
Medium	30	245	15
Diluted viral vector solution	50	250	35
MACS GMP Vectofusin-1 (1000 µg/mL)	2	20	1
Medium	48	230	34
Diluted MACS GMP Vectofusin-1 solution	50	250	35
Cell volume already in culture	100	1500	10 + 20*
Total culture volume after addition of viral vector and MACS GMP Vectofusin-1	200	2000	100

*Extra medium supplied during program activity "Transduction" of the CliniMACS Prodigy T Cell Transduction Process (TCT Process).

5. 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/170-076-165**.

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