



Miltenyi Biotec

# iPS-Brew GMP Medium

iPS-Brew GMP Basal Medium  
iPS-Brew GMP Supplement R

Order no. 170-076-317  
Order no. 170-076-318

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### 1. Description

<b>Components</b>	500 mL iPS-Brew GMP Basal Medium (bottle) 10 mL iPS-Brew GMP Supplement R 50× (10 mL vial)
<b>Main components</b>	Salts, amino acids, vitamins, buffers, proteins
<b>Human proteins</b>	Contains human albumin (pharmaceutical grade).
<b>Specifications</b>	For detailed specifications of the iPS-Brew GMP Basal Medium and the iPS-Brew GMP Supplements R please refer to the respective Product Quality Certificate (PQC).
<b>Total viable aerobic count</b>	No microbial growth.
<b>Transport</b>	iPS-Brew Basal Medium at +2 °C to +8 °C (+36 °F to +46 °F), iPS-Brew Supplement R at -20 °C (-4 °F)
<b>Storage</b>	Store iPS-Brew GMP Basal Medium protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Store iPS-Brew GMP Supplement R at -20 °C (-4 °F).
<b>Shelf life</b>	The use-by date is indicated on the bottle label and vial label, respectively.

### 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 manufacturing and testing of this product is compliant with the requirements laid down in the Ph.Eur. Chapter 5.2.12, if applicable.

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

### 2. Applications

- iPS-Brew GMP Medium has been developed for the maintenance and expansion of human pluripotent stem cells on standard cell attachment matrices, e.g. Laminin 521.

### 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 bottles only.
- ▲ Use undamaged and sealed vials only.
- ▲ Do not use after the use-by date indicated on the bottle and vial label.

### 4. Instructions for use

1. Thaw iPS-Brew GMP Supplement R at +2 °C to +8 °C (+36 °F to +46 °F) overnight.
2. First, add 10 mL iPS-Brew GMP Supplement R (#170-076-318) to 500 mL iPS-Brew GMP Basal Medium (#170-076-317). Mix well.
3. Secondly, add MACS GMP Recombinant Human TGF-β1 (#170-076-166) to a final concentration of 16.8 U/mL.

#### Example:

Reconstitute MACS GMP Recombinant Human TGF-β1 (#170-076-166) according to the data sheet. Use 1 mL of sterile water for injection (WFI) per 5 μg lyophilized MACS GMP Recombinant Human TGF-β1.

The biological activity [U/mg] is lot-specific and stated in the Product Quality Certificate. The dilution factor can be calculated as follows.

Lot-specific activity of example lot:  $1.2 \times 10^7$  U/mg

Total units per 5 µg vial:  $1.2 \times 10^7$  U/mg  $\times$  0.005 mg = 60 000 U

Unit concentration after reconstitution: 60 000 U/mL

In order to obtain a final concentration of 16.8 U/mL, add  $16.8 / 60\,000 \times 500$  mL = 0.140 mL of the reconstituted MACS GMP Recombinant Human TGF-β1.

- Mix well. The medium is ready-to-use now. Use the complete medium within 2 weeks when stored at +2 °C to +8 °C (+36 °F to +46 °F).
- For longer storage, prepare aliquots and store at -20 °C (-4 °F) for up to 2 month. Thaw aliquots of complete medium overnight at +2 °C to +8 °C (+36 °F to +46 °F). Once thawed, keep aliquots at +2 °C to +8 °C (+36 °F to +46 °F) and use within 2 weeks.

## 5. Glossary of symbols

	Manufacturer		Use-by date
	Order number		Protect from sunlight
	Part number		Phone
	Batch code		Fax
	Consult instruction for use		E-mail
	Do not use if package is damaged.		Website

This data sheet and corresponding information as well as special protocols can be found under [www.miltenyibiotec.com/170-076-317](http://www.miltenyibiotec.com/170-076-317) and [www.miltenyibiotec.com/170-076-318](http://www.miltenyibiotec.com/170-076-318).

## 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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