



Miltenyi Biotec

iPS-Brew GMP Medium

2000 mL bag

Order no. 170-076-339

Contents

1. Description
2. Applications
3. Warnings and precautions
4. Instructions for use
5. Glossary of symbols

1. Description

Components	iPS-Brew GMP Basal Medium, 2000 mL bag (#170-076-340) 2× iPS-Brew GMP Supplement, 20 mL bag (#170-076-341)
Main components	Salts, amino acids, vitamins, buffers, proteins
Human Proteins	Contains human albumin (pharmaceutical grade).
Specifications	For detailed specifications of the iPS-Brew GMP Basal Medium and the iPS-Brew GMP Supplement please refer to the respective Product Quality Certificate (PQC).
Total viable aerobic count	No microbial growth detectable.
Transport	iPS-Brew GMP Basal Medium at +2 °C to +8 °C (+36 °F to +46 °F), iPS-Brew GMP Supplement at -20 °C (-4 °F).
Storage	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 at -20 °C (-4 °F).
Shelf life	The use-by date is indicated on the bag 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 designed, manufactured and tested under an ISO 13485 quality management system 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 in compliance with EP chapter 5.2.12 for “Raw materials of biological origin for the production of cell-based and gene therapy medicinal products”.

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 only if bags are undamaged.
- ▲ Do not use after the use-by date indicated on the bag labels.

4. Instructions for use

1. For the preparation of the iPS-Brew GMP Medium thaw the iPS-Brew GMP Supplement at +2 °C to +8 °C (+36 °F to +46 °F) over night.
2. Add the thawed supplement to the iPS-Brew GMP Basal Medium. Weld the tube of the iPS-Brew Basal Medium and iPS-Brew Supplement using a tube welder.
3. Mix well. The medium is ready-to-use now. Store complete iPS-Brew GMP Medium protected from light at +2 °C to 8+ °C (+36 °F to +46 °F). Complete medium can be used up to 2 weeks when stored at +2 °C to 8 °C (+36 °F to +46 °F).
4. The injection and sampling ports of the media bag, including female luer locks and a tube for sterile welding maintain an aseptic workflow, to allow easy and convenient sampling.

5. Glossary of symbols

	Manufacturer		Use-by date
	Order number		Keep away 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/170-076-339.

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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