

MSC-Brew GMP Medium

2000 mL Order no. 170-076-325 500 mL Order no. 170-076-326

Storage Store MSC-Brew GMP Basal Medium

protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Store MSC-Brew GMP Supplement I and MSC-Brew Supplement II

at -20 °C (-4 °F).

Shelf life The use-by date is indicated on the bag and vial

labels.

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.

This product contains human source material and must be treated as potentially infectious. One confidential component is derived from human blood and is tested at the donor level and found nonreactive for HIV-I/II, HIV-NAT, HTLV I/II, HB Ag, HBc, HBVNAT, HCV, HCV-NAT, RPR or FTA-ABS (Syphilis), WNV-NAT, T.cruzi.

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

MSC-Brew GMP Medium has been developed for

- the isolation of MSCs without addition of AB-serum
- the efficient expansion of MSC
- MSCs from human cell sources, such as bone marrow, umbilical cord or adipose tissue

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.

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1. Description

Components MSC-Brew GMP Basal Medium, 2000 mL bag

(#170-076-322)

 $4\times$ 5.0 mL MSC-Brew GMP Supplement I 100×

(vial) (#170-076-323)

 4×5.0 mL MSC-Brew GMP Supplement II $100\times$

(vial) (#170-076-320)

MSC-Brew GMP Basal Medium, 500 mL bag

(170-076-315)

 1×5.0 mL MSC-Brew GMP Supplement I $100\times$

(vial) (170-076-323)

 1×5.0 mL MSC-Brew GMP Supplement II $100\times$

(vial) (170-076-320)

components

Salts, amino acids, vitamins, buffers, proteins

components

Main

Human Proteins Contains human albumin (pharmaceutical

grade).

Specifications

For detailed specifications of the MSC-Brew GMP Basal Medium and the MSC-Brew GMP Supplements I and II please refer to the respective Product Quality Certificate (PQC).

Functionality assay: Isolation and cultivation of mesenchymal stromal or stem cells (MSCs) from human bone marrow by plastic adherence (CFU-F assay) and subsequent expansion of

MSCs.

Total viable aerobic count

No microbial growth detectable.

Transport

MSC-Brew Basal Medium at +2 °C to +8 °C (+36 °F to +46 °F), MSC-Brew Supplement I and MSC-Brew Supplement II at -20 °C (-4 °F).

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- Use only if bags are undamaged.
- ▲ Use only if vials are undamaged and sealed.
- ▲ Do not use after the use-by date indicated on the bag and vial labels

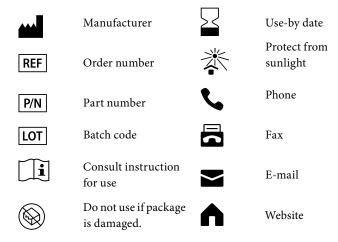
4. Instructions for use

Substrate pre-coating of the culture vessels is not required.

- 1. For the preparation of the MSC-Brew GMP Medium thaw the MSC-Brew GMP Supplements I and II at +2 °C to +8 °C (+36 °F to +46 °F) over night.
- Add the complete vial (500 mL bag) / 4 vials (2000 mL bag) of thawed MSC-Brew GMP Supplements I and II to the MSC-Brew GMP Basal Medium.
- 3. Mix well. The medium is ready-to-use now. Store complete MSC-Brew GMP Medium protected from light at +2 °C to +8 °C (+36 °F to +46 °F).

Complete medium should be used up to 2 weeks when stored at +2 °C to +8 °C (+36 °F to +46 °F).

5. Glossary of symbols



This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/msc-brewgmp-medium.

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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