# HSC-Brew GMP Medium

Order no. 170-076-310

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## 1. Description

| | |
|---|---|
| **Components** | 500 mL HSC-Brew GMP Basal Medium<br>5.0 ml HSC-Brew GMP Supplement 100× |
| **Main components** | Salts, amino acids, vitamins, buffers, proteins |
| **Specifications** | For detailed specifications of the HSC-Brew GMP Basal Medium and the HSC-Brew GMP Supplement please refer to the respective Product Quality Certificate (PQC).<br><br>Functionality assay: *Ex vivo* expansion of human $CD34^+$ cells from cord blood. |
| **Total viable aerobic count** | No microbial growth. |
| **Transport** | At +2 °C to +8 °C (+36 °F to +46 °F) |
| **Storage** | Store HSC-Brew GMP Basal Medium protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Store HCS-Brew GMP Supplement at –20 °C (–4 °F). |
| **Shelf life** | The use-by date is indicated on the bag and 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 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 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

- HSC-Brew GMP Medium has been developed for the cultivation and expansion of human hematopoetic stem cells.

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

## 4. Instructions for use

1. For the preparation of the HSC-Brew GMP Medium thaw the HSC-Brew GMP Supplement at +2 °C to +8°C (+36 °F to +46 °F) for at least 24 h.
2. Please shake the vial gently 2–3 times during thawing procedure. (Some sediments could be observed in the supplement that have no influence on the performance of the medium).
3. Add the complete vial of thawed HSC-Brew GMP Supplement to the HSC-Brew GMP Basal Medium.

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4. Supplement HSC-Brew GMP Medium with HSA to a final concentration of 2% (w/v), i.e. add 43.9 mL of a 25% HSA stock solution to 500 mL HSC-Brew GMP Medium.

5. Store complete HSC-Brew GMP Medium protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Complete medium can be used up to 3 weeks when stored at +2 °C to +8 °C (+36 °F to +46 °F) (Basal Medium + Supplement + HSA). Cultures should be maintained protected from light at 37 °C (+99 °F) in a 5% $CO_2$ atmosphere.

   **Note:** The HSC-Brew GMP Medium does not contain any cytokines or growth factors. These have to be added according to the given protocol.

   **Note:** The HSC-Brew GMP Medium filled in bags can be supplemented, for example, with cytokines or growth factors. Injection and sampling ports, 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 |  | Phone |
|  | Part number |  | Fax |
|  | Batch code |  | E-mail |
|  | Consult instruction for use |  | Website |
|  | Do not use if package is damaged. |  | Protect from sunlight |

This data sheet and corresponding information as well as special protocols can be found under **www.miltenyibiotec.com/170-076-310**.

### Warranty

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