

hyperCryoCell™

Serum-free Cell Freezing Medium



Stem Cells
MSCs, HSCs,
iPSCs, and More

Immune Cells
PBMC, CAR-T, TCR-T, NK,
CAR-NK, DC, and More

Cell Lines
NK-92, CHO,
and More

Protect Your Most
Sensitive Samples

Product Overview

HuaChen Bio hyperCryoCell™ Serum-free Cell Freezing Medium

The hyper-CryoCell Cryopreservation Media Series are pre-formulated, ready-to-use cryoprotectants designed for the preservation of stem cells and immune cell therapy products under ultra-low temperature conditions (-80 ° C and -196 ° C). All products in the series feature serum-free formulations and utilize clinical-grade injectable components. With superior formulation technology, they ensure safe and stable long-term cell storage with high post-thaw viability.

Product Advantages

- Serum-Free
- Animal-Free
- Ready-to-Use
- cGMP Grade
- Chemically Defined
- Clinical-Grade
- -80°C / -196°C Compatible

DMF: 042976



DMF 042976

DMF ACKNOWLEDGEMENT

SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
ATTENTION: ZHENHUA SUN, GENERAL MANAGER
UNIT A3-504-1, CREATIVE INDUSTRY PARK
NO. 328 XINGHU STREET, SUZHOU INDUSTRIAL PARK
SUZHOU CITY, JIANGSU PROVINCE, CHINA

Dear Zhenhua Sun,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED: 042976
DATE OF SUBMISSION: NOVEMBER 19, 2025
DMF TYPE: II
SUBJECT TITLE: SERUM-FREE CELL FREEZING MEDIUM
HOLDER: SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
SUBMITTED BY: SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
AGENT: NONE

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

You are expected to:

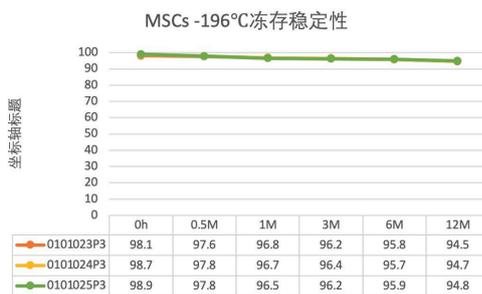
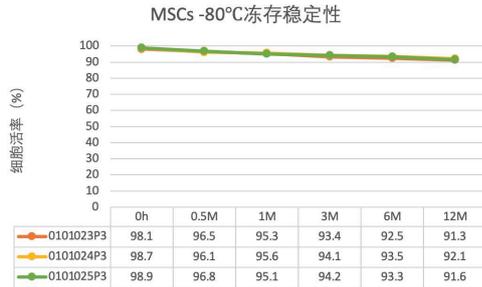
- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
 - Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF (with DMF number) is also not sufficient to authorize that party to reference the DMF.

hyperCryoCell™ Cryopreservation Media – Product List

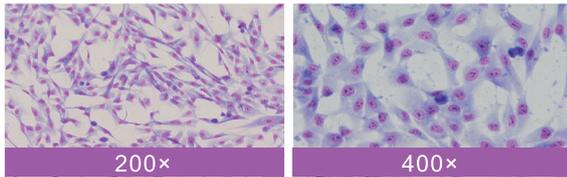
Product Name	Cat. No.	Features	Cell Types
hyperCryoCell03	HCCryo-GMP03	Contains 7.5% injectable-grade DMSO, serum-free, animal-derived component-free, pharmaceutical-grade, ready-to-use pre-mixed cell cryopreservation medium.	Cryopreservation of sensitive cells including stem cells, immune cells (NK, T), iPSCs, and mononuclear cells.
hyperCryoCell04	HCCryo-GMP04	DMSO-free, serum-free, animal-derived component-free, pharmaceutical-grade, ready-to-use pre-mixed cell cryopreservation medium. Clinical injectable grade - ready for infusion without post-thaw washing.	

Product Data

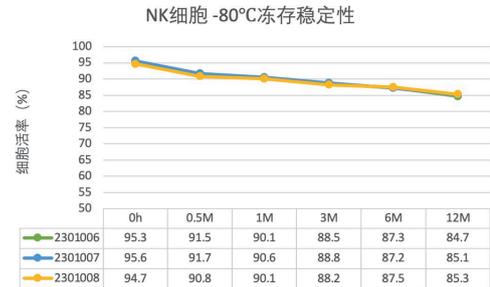
MSC Cryostability



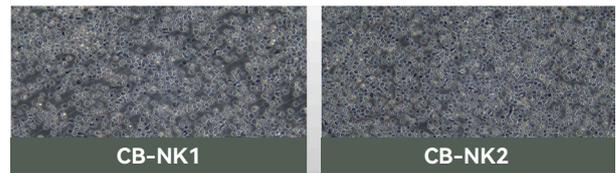
MSC Morphology (Giemsa) After Thawing



NK Cell Cryostability



Umbilical Cord NK Cells – Post-Thaw Microscopy



Instructions for Use

For optimal post-thaw viability, it is recommended to cryopreserve cells during the logarithmic growth phase.

01. Store hyperCryoCell medium at 4°C. Harvest cells, pass through a strainer to obtain a single-cell suspension, and perform cell counting.
02. Wash to remove culture medium. Aspirate the supernatant as thoroughly as possible to avoid diluting the cryopreservation medium.
03. Resuspend cells: Calculate the required volume of hyperCryoCell medium based on cell density (stem cells: 1E6-3E7/mL; immune cells: 1E7-2E8/mL). Add the appropriate volume of hyperCryoCell medium to the cell pellet, gently pipette to resuspend, and aliquot into cryovials or cryobags.
04. Mix by inversion, place in a controlled-rate freezing container, and immediately transfer to a -80°C freezer. Alternatively, use a programmable freezer for controlled nucleation before transferring to liquid nitrogen for long-term storage.

