

hyperCryoCell™

无血清细胞冻存液

Serum-free Cell Freezing Medium



干细胞
MSCs/HSC/iPSCs等

免疫细胞
PBMC/CAR-T/TCR-T/
NK/CAR-NK/DC等

细胞系
NK92/CHO等

其他需要冻存保护的
敏感细胞和组织

产品简介

华辰生物

hyperCryoCell™ 无血清细胞冻存液

hyper-CryoCell系列冻存液为干细胞、免疫细胞治疗用在超低温环境（-80℃与-196℃）保存用生物介质，是预先配置的即用型冷冻保护剂，系列产品均采用无血清技术配方，均采用临床注射级成分，配方优越，可支持细胞长期储存，安全稳定，复苏活率高。

产品优势

- 无血清
- 无动物源成分
- 即用型
- cGMP制造
- 化学成分明确
- 临床注射级成分
- 80℃与-196℃兼容

DMF备案号: 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:

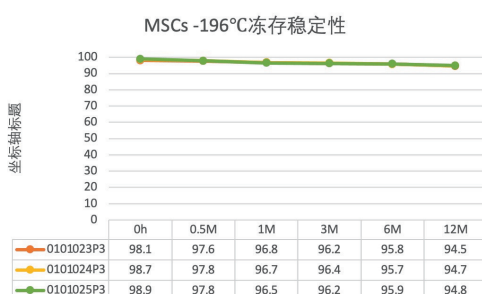
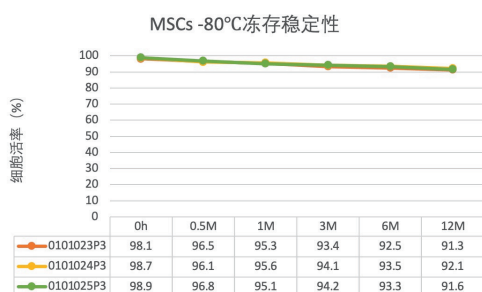
- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
 - Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report 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™ 系列冻存液产品清单

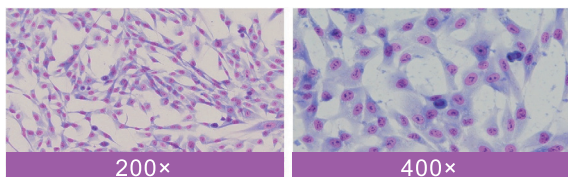
品名型号	货号	特点	适用类型细胞
hyperCryoCell03	HCCryo-GMP03	含7.5%注射剂DMSO，无血清，无动物源成分，药用级组分，预混式即用型细胞冻存液。	干细胞、免疫细胞（NK、T）、iPSC、单个核细胞等敏感类细胞低温冻存
hyperCryoCell04	HCCryo-GMP04	无DMSO、无血清、无动物源成分，药用级组分，预混式即用型细胞冻存液。临床注射级，复苏免洗涤回输。	

产品数据展示

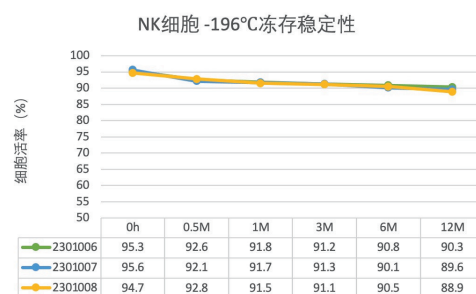
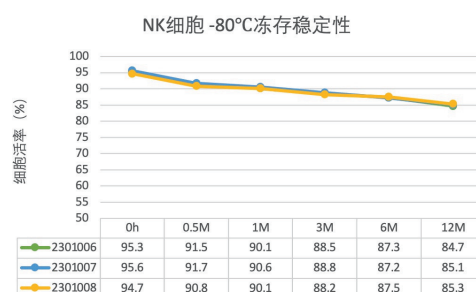
MSCs冻存稳定性实验



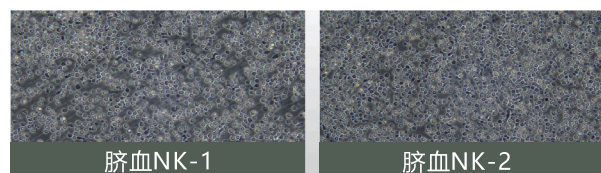
MSCs细胞冻存复苏后,吉姆萨染色形态特征鉴定



NK细胞冻存稳定性实验



脐带NK细胞冻存复苏后显微镜观察图



使用方法

建议冻存处于对数生长期的细胞，有助于提高复苏细胞活率。

01. 细胞冻存液4°C保存，收获细胞并过筛网成单细胞，计数细胞数量。
02. 洗涤去除培养基，尽可能去除上清，以免稀释细胞冻存液。
03. 重悬细胞：干细胞按照1E6-3E7/ml，免疫细胞按照1E7-2E8/ml，细胞密度计算所需冻存液体积。向细胞沉淀中加入适量hyperCryo-Cell细胞冻存液，轻轻吹打以重悬细胞，分装于细胞冻存管或冻存袋中。
04. 颠倒混匀后，置于程序降温盒，立即放入-80°C冰箱，或使用程序降温仪冷冻成核，移入液氮罐中长期储存。

