



Huachenbio -- Your Professional Choice!

苏州华辰生物科技有限公司

Suzhou Huachen Biotechnology Co., Ltd

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WeChat Official Account



WeChat Official Subscription Account



WeChat ID for Inquiries



- ◆ Suitable for Primary Cell Isolation and Subculture
- ◆ Compatible with a variety of mesenchymal stem cells, such as umbilical cord-, adipose-, bone marrow-, amniotic membrane-, hair follicle-, and dental pulp-derived mesenchymal stem cells
- ◆ Serum-free, free of any animal-derived components, antibiotic-free, stable in performance, and minimal batch-to-batch variation
- ◆ High cell expansion rate, with a single passage expansion fold of over 20x
- ◆ Cell yield per T175 flask: $>2 \times 10^7$ cells;
Cell yield per 10-layer cell factory: $8-10 \times 10^8$ cells
- ◆ Cell diameter: 14-15 μm , smaller than that of similar products on the market
- ◆ GMP level, prepared with water for injection (WFI), endotoxin < 0.1 EU/ml
- ◆ Independent R&D and production system, stable supply, and high cost-effectiveness
- ◆ Scalability proven for 3D microcarrier culture (10L/50L)



novastem-MSC[®]

间充质干细胞无血清培养基

Serum-Free Medium For Mesenchymal Stem Cell

COMPANY PROFILE

Suzhou Huachen Biotechnology Co., Ltd.

Founded by seasoned technical experts with years of deep engagement in the Cell and Gene Therapy (CGT) field, Suzhou Huachen Biotechnology stands as a leader in providing comprehensive end-to-end solutions for the CGT industry. The company focuses on the R&D, production, and sales of high-end reagents for the CGT sector, offering clients high-quality reagents that serve as reliable domestic alternatives, along with integrated solutions for cell therapy process development.

Huachen Biotechnology has been certified under the ISO9001 Quality Management System, with multiple products having obtained U.S. FDA DMF numbers. Recognized as an Enterprise Led by Pioneering Talent in Suzhou Industrial Park and a National High-tech Enterprise, the company serves as a Governing Board Member of the China Medical Biotechnology Association and a Vice-Chair unit of its Sub-branch for Skin Soft Tissue Repair and Reconstruction Technology. Additionally, it is recognized as a Technology-based SME and a Jiangsu Provincial Private Technology Enterprise, having filed for over a dozen invention patents.

The company has now established a comprehensive product portfolio, including:

Stem Cell Media: Serum-free and chemically defined media for stem cell culture; Fibroblast Media: Fibroblast culture medium; Immune Cell Media: Serum-free media for T cells and NK cells; NK Cell Kits: High-efficiency NK cell activation and expansion kits; $\gamma\delta$ T Cell Kits: $\gamma\delta$ T cell activation and expansion kits; iNKT Cell Kits: iNKT cell kits; iPSC Solutions: iPSC culture media and enzyme-free passaging solutions; 3D Culture Products: Stem cell 3D StarPore microcarriers and mini-bioreactors; Cryopreservation: Serum-free cell cryopreservation media, and more.

Manufacturing & Development Capabilities

Stem Cell and Immune Cell Media Production Base: Automated production line with 1,000L capacity.

R&D and Production Facilities: 2,500 m² of laboratory space, housing production facilities for kits and 3D microcarriers.

Grade B GMP Laboratories: Providing comprehensive process development solutions and services.

Robust Quality System: Meeting client requirements for on-site audits and supporting IND application filings.

PRODUCT INTRODUCTION

novastem-MSc Serum-Free Medium For Mesenchymal Stem Cell

It can be used for the primary cell isolation and subculture of mesenchymal stem cells (MSCs) from multiple sources, such as umbilical cord (UCMSCs), adipose tissue (ADSCs), bone marrow (BMSCs), amniotic membrane (AMSCs), hair follicles (HFSCs), dental pulp (DPSCs), etc., while maintaining the cells' pluripotent differentiation potential.

It is serum-free, free of any animal-derived components, and antibiotic-free, with stable performance and minimal batch-to-batch variation.

It features a high cell expansion rate, with the cell count at the same passage being significantly higher than that of similar products on the market.

It has an independent R&D and production system, ensuring stable supply and high cost-effectiveness.

It supports clinical-grade / pharmaceutical-grade cell culture.

USAGE INSTRUCTIONS



01

02

03

● It is recommended that the supplement be thawed at 37°C.

● Add it to the medium and mix thoroughly until uniform.

● Prepare a complete medium

Tips: Pay attention to the thawing time; it is optimal to leave a few small ice crystals when thawing is nearly complete. For small-volume use, aliquot and store the supplement in frozen state.

It is recommended that the complete medium be prepared right before use and used up within one month.

If the culture system is small, it is advisable to aliquot the supplement into smaller portions for frozen storage based on actual usage. Prepare the complete medium in proportion when needed to avoid repeated freeze-thaw cycles.

Seeding Density



6000-7000 PCS/cm²

P1 P7



7000-8000 PCS/cm²

P8 P10



8000-9000 PCS/cm²

P11 P13



9000-10000 PCS/cm²

P14 and above

Cell Passage Time

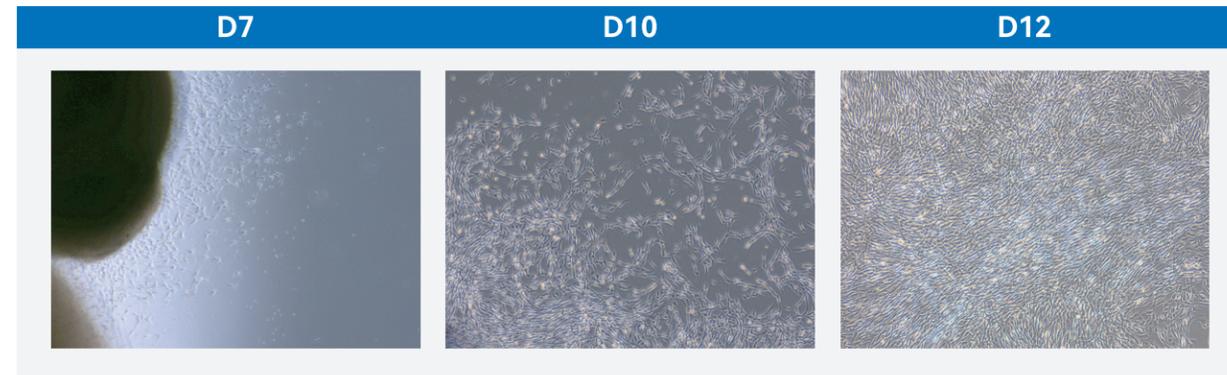
It is generally around 3 days (72 hours). The proliferation rate of different human Mesenchymal Stem Cells (hMSCs) varies. It is recommended to determine the exact passage time based on cell confluency; passage is advised when cell confluency reaches approximately 80-90%. Excessive cell confluency (>95%) will affect subsequent cell growth.

Cell Morphology

The cells are spindle-shaped and exhibit a swirling (or vortex-like) growth pattern.

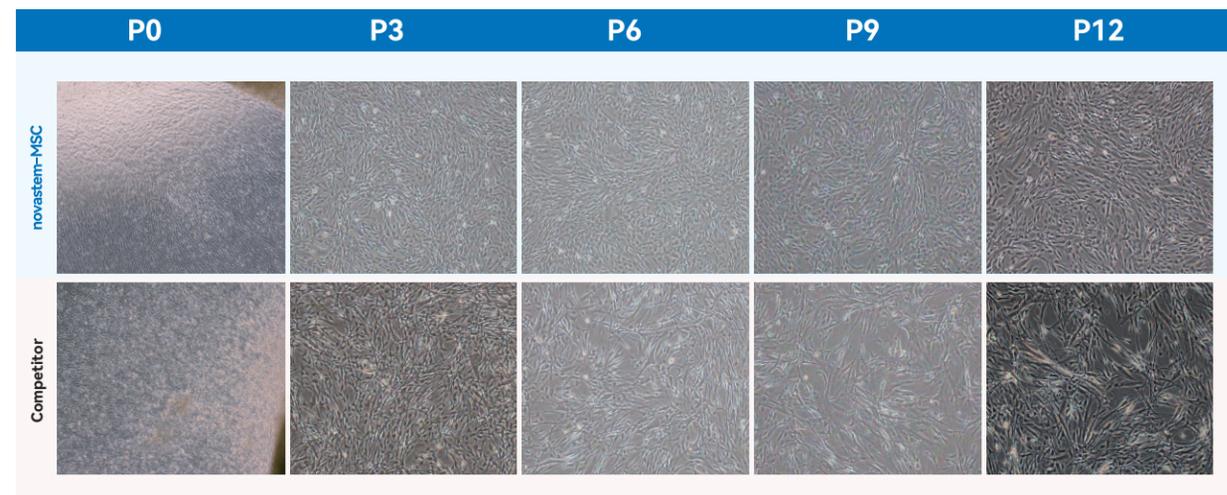
CULTURE OF MESENCHYMAL STEM CELLS

Primary Culture



- ✓ Isolate the Wharton's jelly tissue from the umbilical cord and perform primary culture using the tissue block adherence method. Inoculate 0.5g of Wharton's jelly into each T75 culture flask. After culturing in a 37°C cell incubator for 1-2 hours, add 6-8ml of cell culture medium. Supplement with 5ml of medium on days 2-3. Change the medium on days 7-10 by discarding the supernatant and adding 10-15ml of fresh medium. Observe the cell expansion on days 12-14 and proceed with digestion and passage.
- ✓ The earliest time for cells to migrate out of the tissue blocks is 5-7 days, and a small number of scattered cells can be observed under the microscope.
- ✓ The tissue block adherence efficiency is high, with a large number of tissue blocks adhering to the culture surface.
- ✓ A greater number of cells can be harvested.

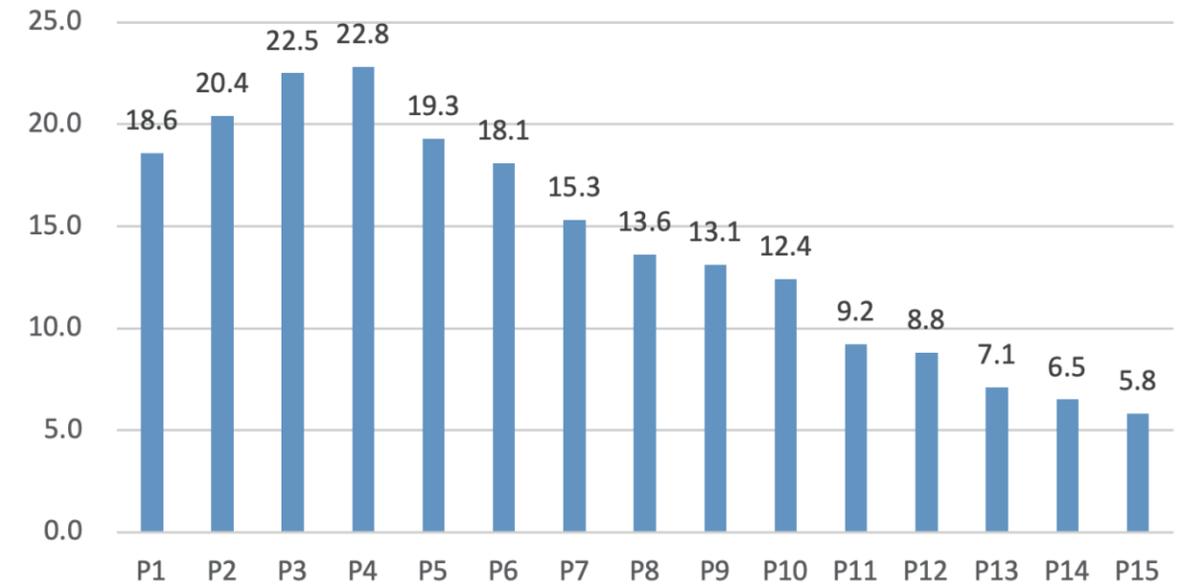
Subculture



- Compared with similar products on the market, it has higher expansion efficiency. The cells at high passages age more slowly and can support culture for more than 20 passages.

Culture Performance

Expansion fold of novastem-MSC medium during passage



Passage	Seeding Density (cells/cm ²)	Time	Culture Vessels	Harvested Cell Count (cells/flask)	Expansion Fold	Total Cell Number	Total Expansion Fold
P0	-	10-14天	T75	1.00E+06	-	2.00E+07	-
P1	7000	72h	T175	2.28E+07	18.6	3.72E+08	18.6
P2	7000	72h	T175	2.50E+07	20.4	7.59E+09	379.44
P3	7000	72h	T175	2.76E+07	22.5	1.71E+11	8537.4
P4	7000	72h	T175	2.79E+07	22.8	3.89E+12	194652.72
P5	7000	72h	T175	2.36E+07	19.3	7.51E+13	3756797.496
P6	7000	72h	T175	2.28E+07	18.1	1.36E+15	67998034.68
P7	7000	72h	T175	2.00E+07	16.3	2.22E+16	1108367965
P8	8000	72h	T175	2.10E+07	15.0	3.33E+17	16625519479
P9	8000	72h	T175	1.93E+07	13.8	4.59E+18	2.29432E+11
P10	8000	72h	T175	1.74E+07	12.4	5.69E+19	2.84496E+12
P11	9000	72h	T175	1.61E+07	10.2	5.80E+20	2.90186E+13
P12	9000	72h	T175	1.54E+07	9.8	5.69E+21	2.84382E+14
P13	9000	72h	T175	1.28E+07	8.1	4.61E+22	2.30349E+15
P14	10000	72h	T175	1.14E+07	6.5	2.99E+23	1.49727E+16
P15	10000	72h	T175	1.02E+07	5.8	1.74E+24	8.68418E+16

- The average expansion fold of the Novastem-MSC system from P1 to P5 is 20.7.
- Counted on average from 10 umbilical cords: for example, if approximately 10g of Wharton's jelly tissue is isolated, 2.0×10⁷ cells can be obtained at Passage 0 (P0), and theoretically 1.71×10¹¹ cells can be obtained at Passage 3 (P3).
- When prepared into products at the conventional dosage of 5×10⁷ cells per unit, it can yield 3,420 units in total.

Summary

Cell Passage Time

It is generally around 3 days (72 hours). Different hMSCs vary in their growth rates. It is recommended to determine the exact passage timing based on cell confluency; passage is advised when cell confluency reaches approximately 80%-90%. Excessively high cell confluency (>95%) will affect subsequent cell growth.

The medium volume is 0.2 mL/cm². No coating is required, and no medium change is needed for 3 consecutive days of culture.

When switching from other culture systems to novastem-MSC, the initial cell expansion fold may be relatively low. It is recommended to resuscitate and seed cells with a 1:1 mixture of the original medium and novastem-MSC. After 1 generation of culture, the system can be completely switched to novastem-MSC.

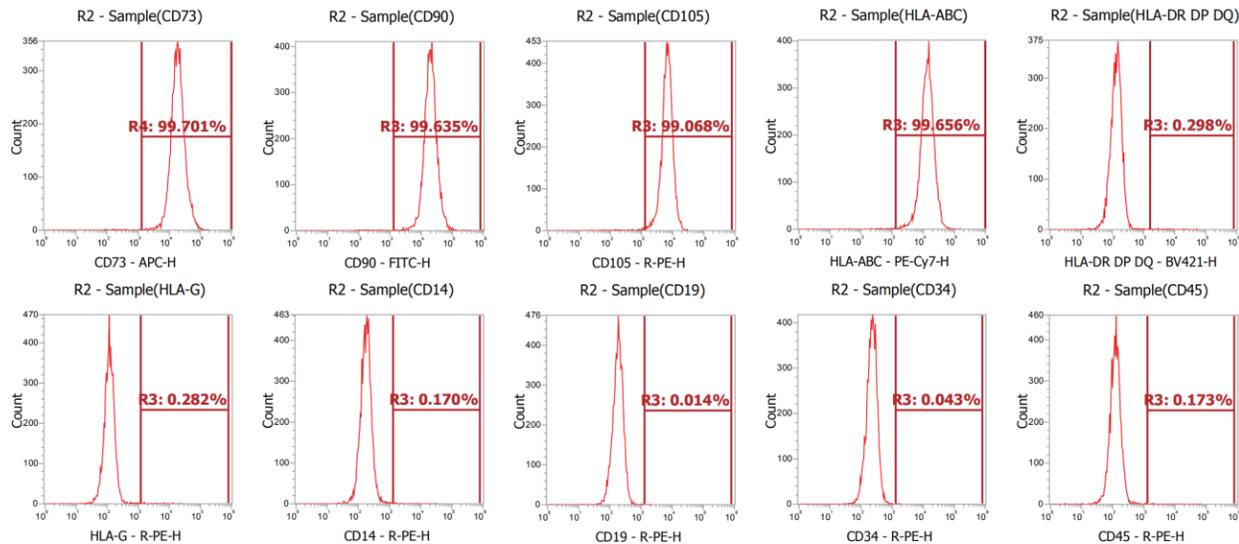
Cell Digestion

It is recommended to use a relatively gentle trypsin, such as Gibco TrypLE™ Express Enzyme (recombinant, 1X). Dilute it with PBS at a 1:1 ratio to prepare a working solution of trypsin before use. The digestion time is 3-5 minutes. After 1-2 minutes of digestion, gently tap the culture vessel; when most cells are observed to detach, terminate the digestion with medium.

Cell Cryopreservation

It is recommended that the final concentration of DMSO be 5%. Before cell digestion, you can first prepare a cryopreservation solution with a volume ratio of DMSO to complete medium of 1:9, and store it pre-cooled at 2-8°C. After the cells to be cryopreserved are mixed with complete medium, slowly add an equal volume of the pre-prepared cryopreservation solution, mix well, and then aliquot for cryopreservation.

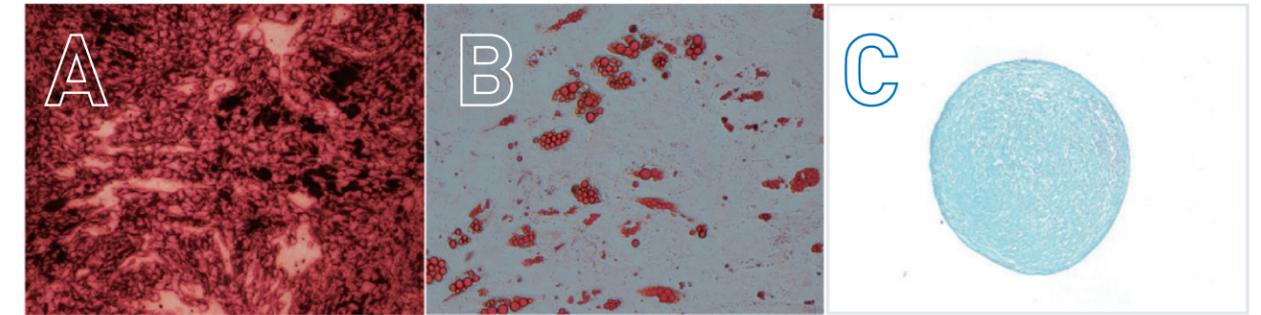
Detection of Cell Surface Markers



Detection of Surface Markers in Cultured hMSCs

The positive rates of CD73, CD90, CD105, and HLA-ABC are >95.0%;
The positive rates of CD14, CD19, CD34, CD45, and HLA-DRDPDQ are ≤2.0%.

Cellular Multilineage Differentiation Potential



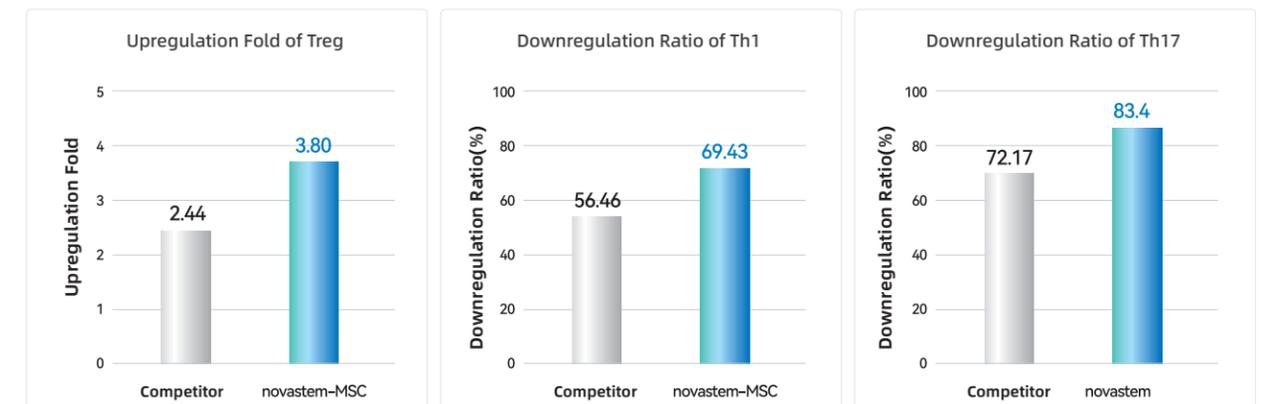
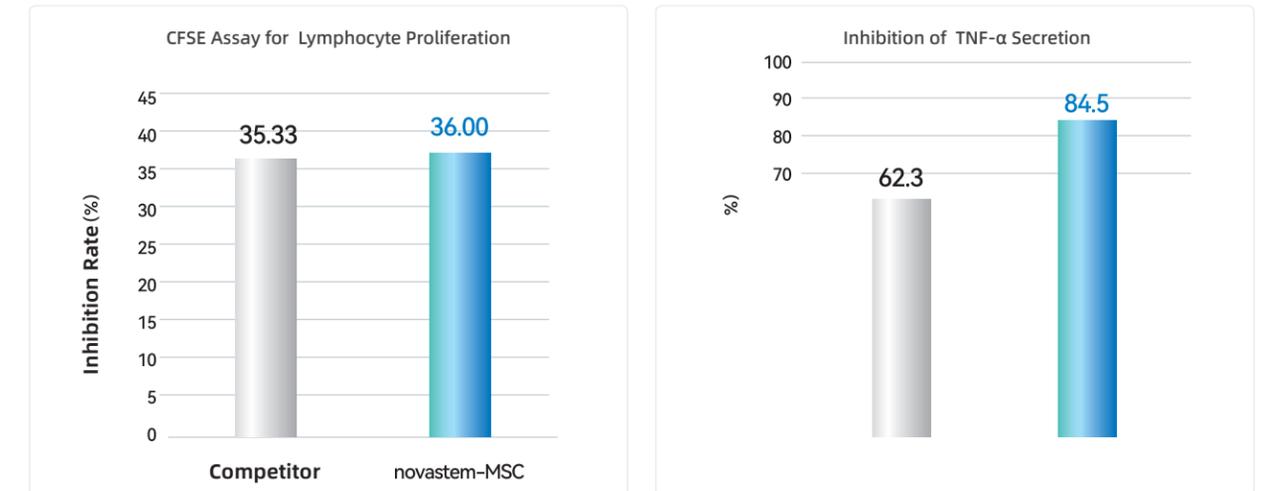
Three-Lineage Differentiation Assays:

A Osteogenic differentiation (Alizarin Red staining)

B Adipogenic differentiation (Oil Red O staining)

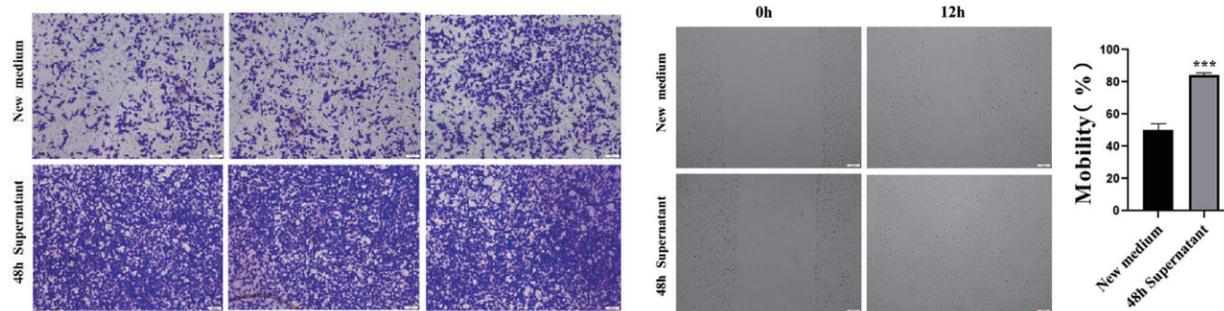
C Chondrogenic differentiation (Alcian Blue staining)

Detection of Cellular Immunomodulatory Capacity

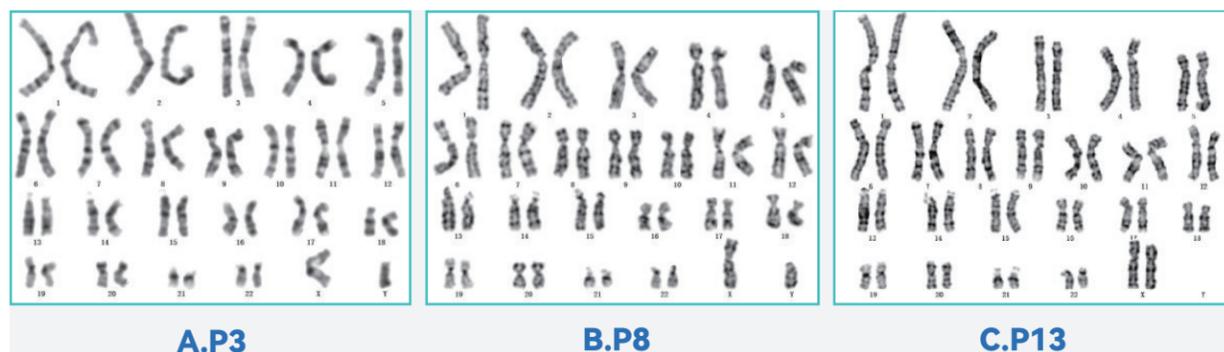


Cultured hMSCs demonstrate immunomodulatory functions including inhibition of lymphocyte proliferation, upregulation of Tregs, downregulation of Th1 and Th17 responses, and suppression of TNF-α expression.

Detection of Cell Migration Ability Detection of Angiogenic Ability



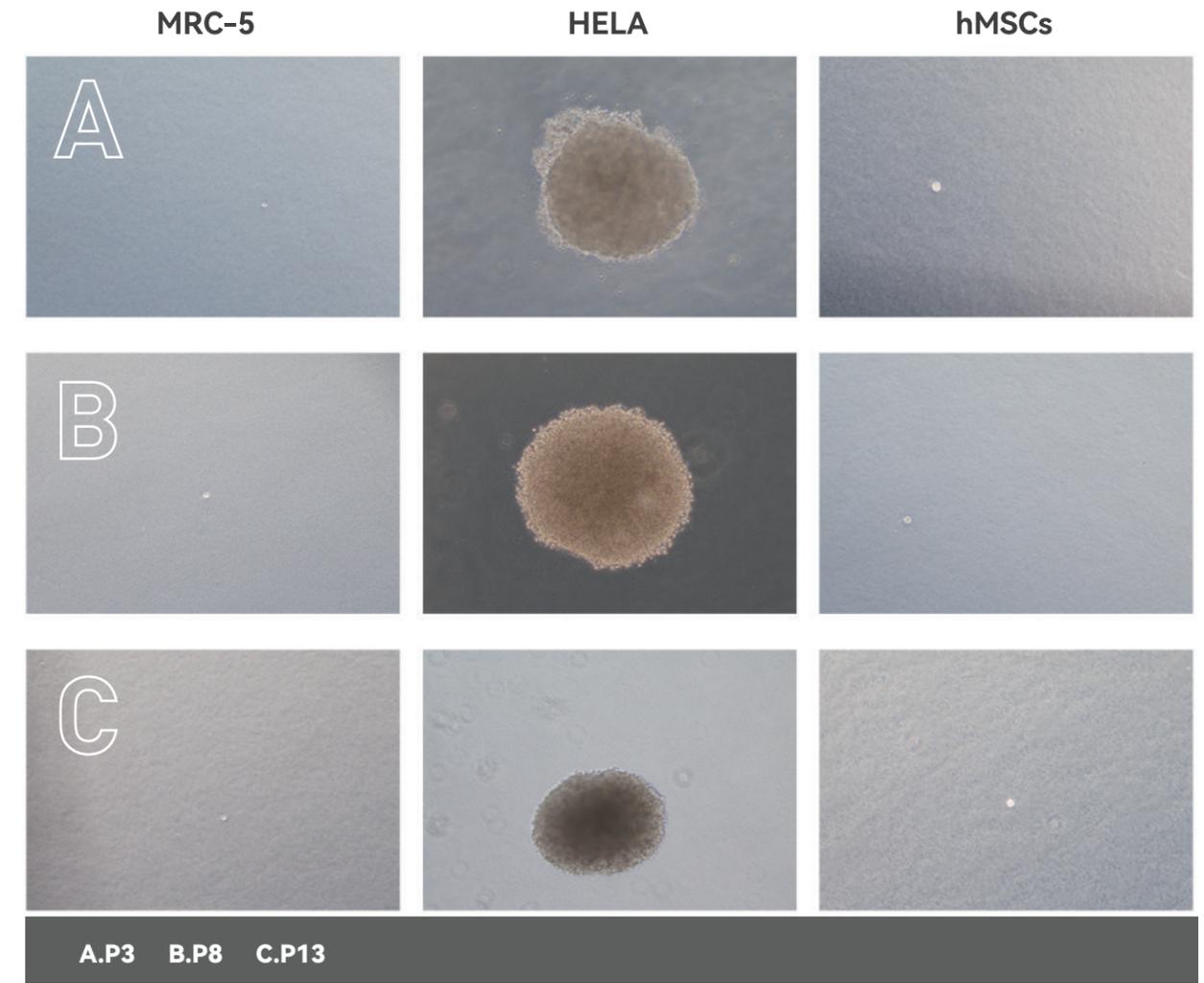
Karyotype Analysis of Cell Chromosomes



Karyotype Analysis Results of Continuously Cultured hMSCs:

No numerical or structural abnormalities of chromosomes were observed.

In Vitro Tumorigenicity Assay of Cells



Results of In Vitro Tumorigenicity Assay for Continuously Cultured hMSCs:

Human Mesenchymal Stem Cells (hMSCs) failed to form colonies in the soft agar colony formation assay, indicating that they do not possess tumorigenic potential in vitro.

连续培养的hMSCs体外成瘤性试验结果:

hMSCs在软琼脂克隆法中均无法形成克隆, 提示其在体外不具备成瘤性。

Novastem-MSC Serum-Free Medium - Quality Control Report

Report Date: 2025-12-19

CERTIFICATE OF ANALYSIS 产品检测报告

Product: Serum-Free Mesenchymal Stem Cell	REF: HC-UC02F
产品名称: Medium Without Phenol Red	货号: HC-UC02F
Volume: 500ml	LOT: 20251206
规格: 500ml	批号: 20251206
Storage: store at 2-8°C for 12 Months	EXP: 2026-11
储存: 2-8°C 避光 12个月	有效期至: 2026-11

TESTS 检测项	SPECIFICATIONS 标准	RESULTS 结果
Appearance (Turbidity) 外观(浑浊度)	Clear 澄清	Clear 澄清
Appearance (Form) 外观(形态)	Solution 液体	Solution 液体
pH (Undiluted) pH(未稀释)	7.0-7.4	7.26
Osmolality (mOsm/kg) 渗透压(mOsm/kg)	280-350	301
Sterility 无菌	Negative 无	Negative 无
Endotoxin Level (EU/ml) 内毒素(EU/ml)	<0.5	<0.100
Mycoplasma 支原体	Negative 无	Negative 无
Cell culture testing 细胞培养测试	PASS 通过	PASS 通过

Edited by: 何清梅
Checked by: 王欢
Approved by: 王欢

A medium for in vitro culture of human mesenchymal stem cells. Does not contain antimicrobial agents. DMF: 039951. 一种用于体外培养人间充质干细胞的培养基。不含抗生素。DMF 备案号: 039951。

Report Date: 2026-01-05

CERTIFICATE OF ANALYSIS 产品检测报告

Product: Basal Medium Supplement	REF: HC-UC02S
产品名称: Basal Medium Supplement	货号: HC-UC02S
Volume: 25ml	LOT: 20251215
规格: 25ml	批号: 20251215
Storage: store at -20°C for 12 Months	EXP: 2026-11
储存: -20°C 避光 12个月	有效期至: 2026-11

TESTS 检测项	SPECIFICATIONS 标准	RESULTS 结果
Appearance (Turbidity) 外观(浑浊度)	Clear 澄清	Clear 澄清
Appearance (Form) 外观(形态)	Solution 液体	Solution 液体
pH (Undiluted) pH(未稀释)	7.0-7.5	7.30
Osmolality (mOsm/kg) 渗透压(mOsm/kg)	220-320	255
Sterility 无菌	Negative 无	Negative 无
Endotoxin Level (EU/ml) 内毒素(EU/ml)	<0.5	<0.100
Mycoplasma 支原体	Negative 无	Negative 无
Cell culture testing 细胞培养测试	PASS 通过	PASS 通过
Virus test 病毒测试	Negative 无	Negative 无

Edited by: 何清梅
Checked by: 王欢
Approved by: 王欢

① Endotoxin specification for working concentration. 内毒素指标为工作浓度指标。
② Viral test results by tNGS are in the attached report. 病毒测试使用 tNGS 法, 结果见附件报告。

Regulatory Compliance File: Novastem-MSC

DMF:039951

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Silver Spring, MD 20993

DMF 039951
DMF ACKNOWLEDGEMENT

SUZHO HUACHEN BIOTECHNOLOGY CO LTD
ATTN: ZHENHUA SUN, GENERAL MANAGER
ROOM 5F-578, BLOCK B, TONGCHENG BUILDING
NO. 188 YUXIN ROAD, 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: 039951
DATE OF SUBMISSION: JUNE 03, 2024
DMF TYPE: II
SUBJECT (TITLE): SERUM-FREE MESENCHYMAL STEM CELL 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Silver Spring, MD 20993

DMF 039951
DMF ACKNOWLEDGEMENT

SUZHO HUACHEN BIOTECHNOLOGY CO LTD
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SUBMITTED BY: SUZHOU HUACHEN BIOTECHNOLOGY CO LTD
AGENT: NONE

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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.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at <https://www.fda.gov/drugs/development-approval-process/new-drugs-nda/submitting-a-dmf>

The holder of the DMF is responsible for compliance with 21 CFR 314.420 as interpreted in "The Guidance for Drug Master Files" at <https://www.fda.gov/drugs/development-approval-process/new-drugs-nda/submitting-a-dmf>

CERTIFICATE OF REGISTRATION 认证证书

证书编号: J24Q2528029253R05
苏州华辰生物科技有限公司
SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.

质量管理体系符合 GB/T19001-2016/ISO9001:2015 认证范围: 细胞技术的研发和应用

发证日期: 2024年02月06日
有效期至: 2026年02月07日

发证机构: 方圆标志认证集团有限公司

CERTIFICATE OF REGISTRATION 认证证书

证书编号: J24Q2528029253R05
苏州华辰生物科技有限公司
SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.

质量管理体系符合 GB/T19001-2016/ISO9001:2015 认证范围: 细胞技术的研发和应用

发证日期: 2024年02月06日
有效期至: 2026年02月07日

发证机构: 方圆标志认证集团有限公司

病原体微生物靶向基因(tNGS(439种))检测报告(简易版)

姓名: HC-UC02S 20251215	性别: /	年龄: /
住院号/门诊号: 20251230005	电话: /	床号: /

样本编号: T20251230005	检测项目: SX0012	样本类型: 无菌液体
采样日期: 20251229	接收日期: 20251230	样本体积: /

送检医院: 苏州华辰生物科技有限公司
送检科室: /
送检医生: /

细菌	真菌	病毒	其他病原体	耐药基因	毒力基因
未检出	未检出	未检出	未检出	未检出	未检出

检测者: 桂树西 审核者: 王欢 报告日期: 2025-12-30

无锡名泽医学检验实验室
本检测报告为简易版, 详细结果见正式报告单。如对结果有疑问, 请在一周内与我司联系(自报告日期起算)
联系电话: 17715806311或4000510481; 地址: 无锡市梁溪区苏锡路2-7号三楼

- Higher Quality Standard for MSC Serum-Free Medium
- Endotoxin: <0.1 EU/mL
- Pathogen testing by tNGS (439 targets)
- IND and clinical applications assured

Ordering Information

Kit Name	Kit Cat#	Product Components	Product Cat#	Specs	Qty
Serum-Free Medium For Mesenchymal Stem Cell Kit	HC-UC02R5-kit	novaStem-MSC Serum-Free Medium For Mesenchymal Stem Cell(with Phenol Red)	HC-UC02R	500ml/bottle	1
	HC-UC02S5-kit	novaStem-MSC Basal Medium supplement	HC-UC02S	25ml/bottle	1
Serum-Free Medium For Mesenchymal Stem Cell Kit	HC-UC02F5-kit	novaStem-MSC Serum-Free Medium For Mesenchymal Stem Cell(without Phenol Red)	HC-UC02F	500ml/bottle	1
	HC-UC02S5-kit	novaStem-MSC Basal Medium supplement	HC-UC02S	25ml/bottle	1