



Huachenbio -- Your Professional Choice

苏州华辰生物科技有限公司

Suzhou Huachen Biotechnology Co., Ltd

Tel: 400-965-9800

Website: www.huachenbiotech.com

Address: Unit A3-504-1, Creative Industry Park, No. 328 Xinghu Street, Suzhou Industrial Park



WeChat
Official Account



WeChat Official
Subscription Account



WeChat ID
for Inquiries



Partner for End-to-End CGT Solutions



- ✦ Serum-Free, Platelet Lysate-Free
- ✦ Animal-Derived Component-Free
- ✦ Human-Derived Component-Free, Contains Recombinant Human Serum Albumin (rHSA)
- ✦ Chemically Defined, High Batch-to-Batch Consistency
- ✦ High Efficiency, Supporting Primary and Passage Cultures of MSCs
- ✦ Manufactured in Compliance with GMP Standards, Supporting Pharmaceutical Registration
- ✦ Higher Quality, Endotoxin < 0.1 EU/mL



StarMedium® MSC

新一代间充质干细胞化学成分限定培养基


Chemically Defined Medium For Mesenchymal Stem cell

StarMedium® MSC

Chemically Defined Medium For Mesenchymal Stem cell


StarMedium® MSC CD Medium is developed and manufactured based on advanced medium formulations and production technologies. Produced in compliance with GMP standards, it enables a seamless transition from your research and development stage to industrialized clinical applications.

Why Choose StarMedium® MSC CD Medium?




Serum-free

Serum-Free, Platelet Lysate-Free, "Genuine Serum-Free"




Animal origin-free

Animal-derived component-free, which minimizes the risk of pathogen infection, reduces immunogenic reactions, and ensures higher safety




Xeno-free

Human-Derived Component-Free, Contains Recombinant Human Serum Albumin (rHSA), with Controllable Raw Material Quality




Chemically Defined

All component sources and purities are known and clear, with chemically defined composition.



High Batch-to-Batch Consistency

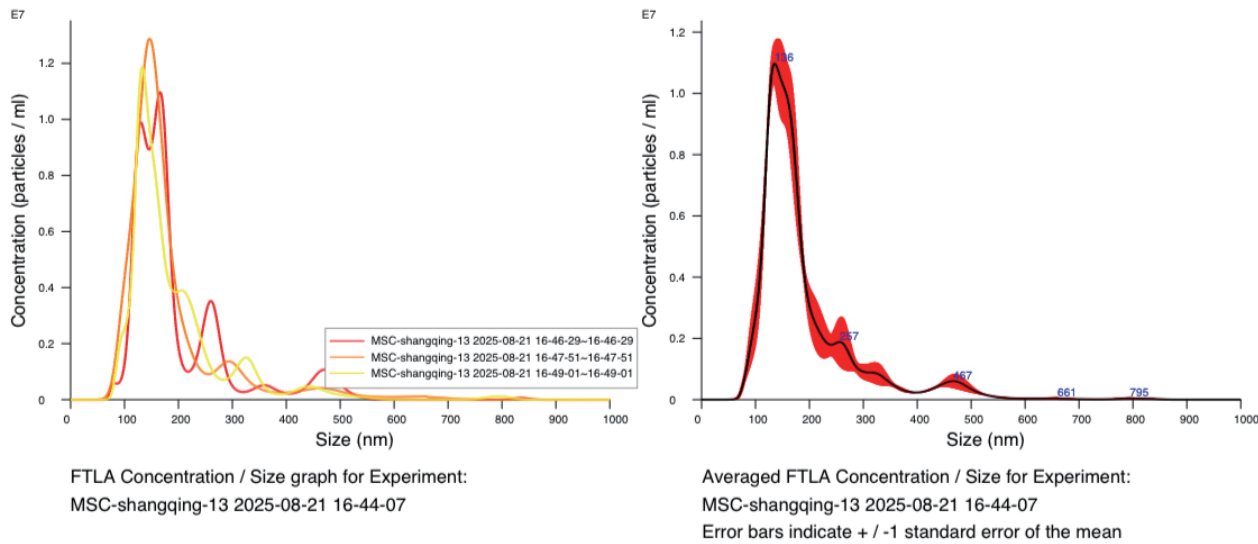
Raw materials can be produced in large quantities with standardization, ensuring minimal batch-to-batch variation and reproducible performance from the research stage to large-scale production.



**High Performance
High Quality
High Yield**

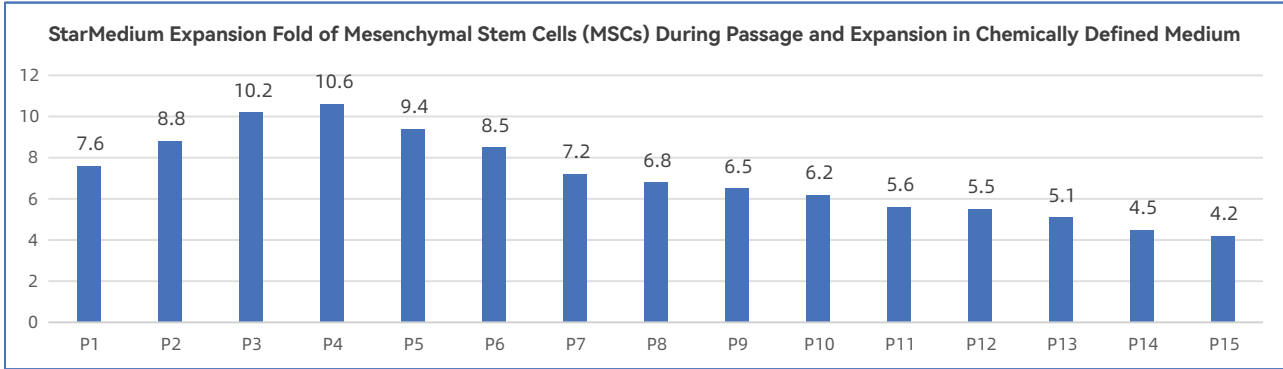
① Excellent cell proliferation performance and cell morphology;
② Endotoxin content < 0.1 EU/mL, which can reduce the number of washing steps and improve cell yield;
③ Batch yield is not limited by serum substitutes, with stable components enabling large-scale production.

Exosome Particle Count Assay Chart



Expansion Fold

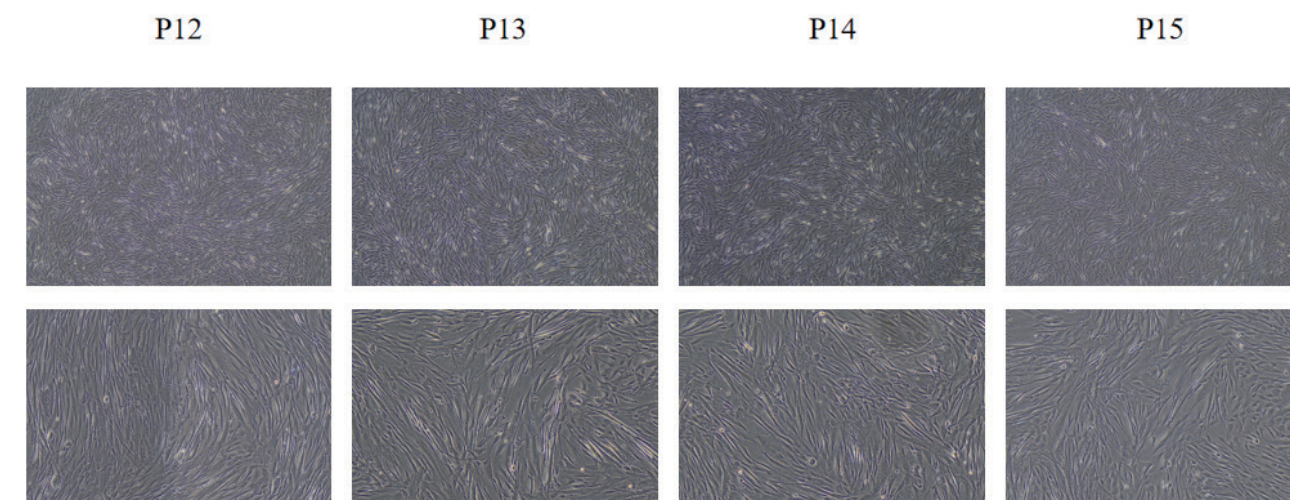
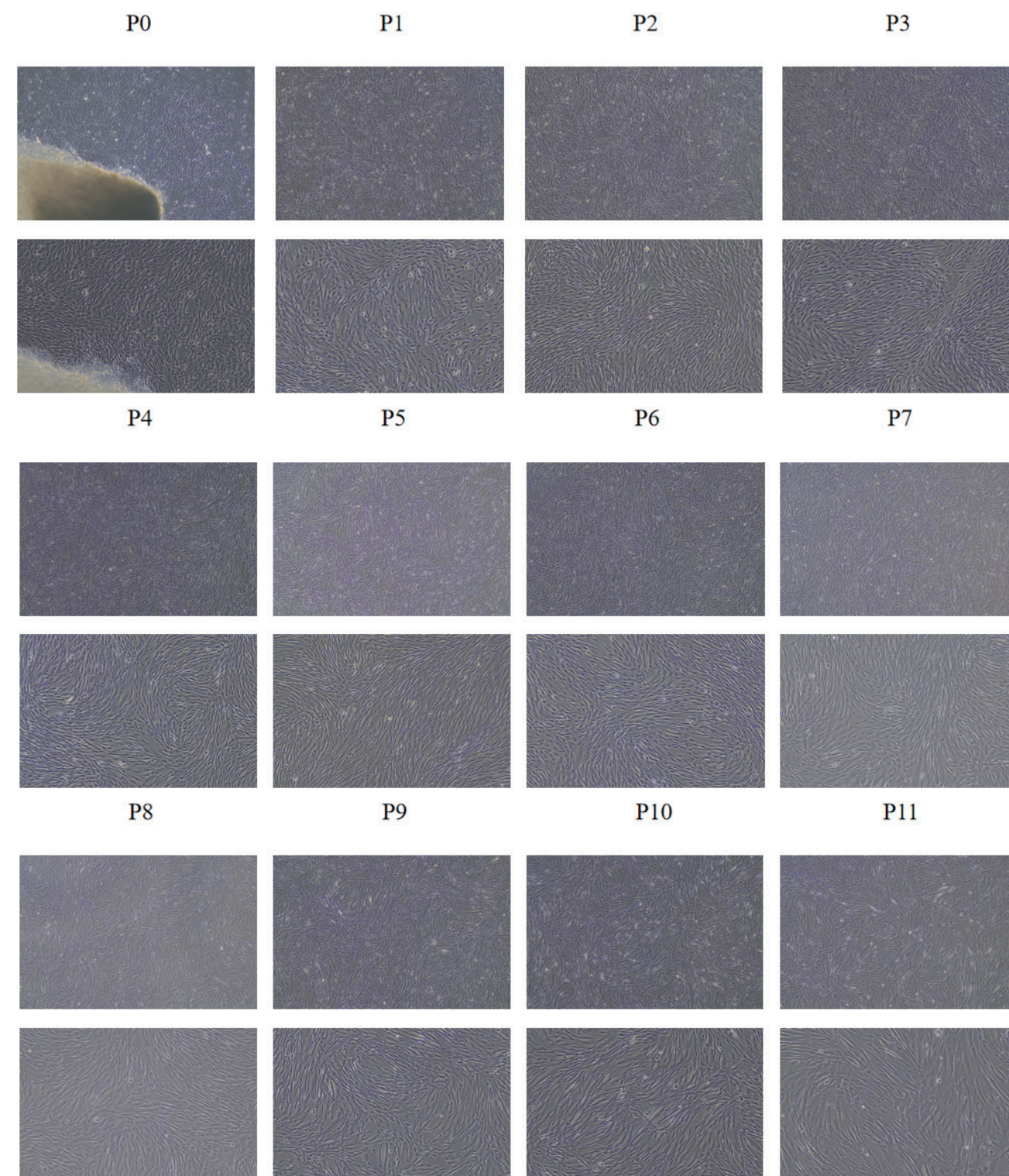
StarMedium Continuous Passage of Mesenchymal Stem Cells (MSCs) in Chemically Defined Medium					
Passage	Seeding Density cells / cm ²	Culture Container	Harvested Cell Number (cells/bottle)	Expansion Fold	Total Expansion Fold
P0	-	T75	5.00E+05	-	-
P1	10000	T175	1.33E+07	7.6	7.6
P2	10000	T175	1.54E+07	8.8	66.88
P3	10000	T175	1.79E+07	10.2	682.176
P4	10000	T175	1.86E+07	10.6	7231.0656
P5	10000	T175	1.65E+07	9.4	67972.01664
P6	11000	T175	1.64E+07	8.5	577762.1414
P7	11000	T175	1.39E+07	7.2	4159887.418
P8	11000	T175	1.31E+07	6.8	28287234.44
P9	12000	T175	1.37E+07	6.5	183867023.9
P10	12000	T175	1.30E+07	6.2	1139975548
P11	12000	T175	1.18E+07	5.6	6383863070
P12	13000	T175	1.25E+07	5.5	35111246882
P13	13000	T175	1.16E+07	5.1	1.79067E+11
P14	13000	T175	1.02E+07	4.5	8.05803E+11
P15	14000	T175	1.03E+07	4.2	3.38437E+12



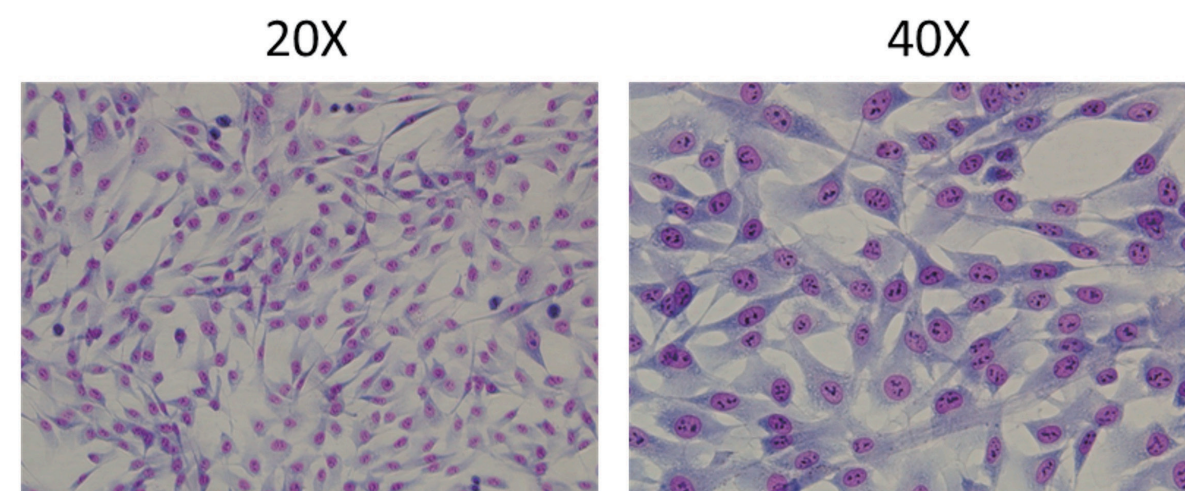
	Average Particle Concentration/ml
Complete Medium	3.60E+08
72-Hour Culture Supernatant	1.83E+09

UC-MSC Cell Culture Micrograph

Spiral cell clusters with directionality and good cell morphology

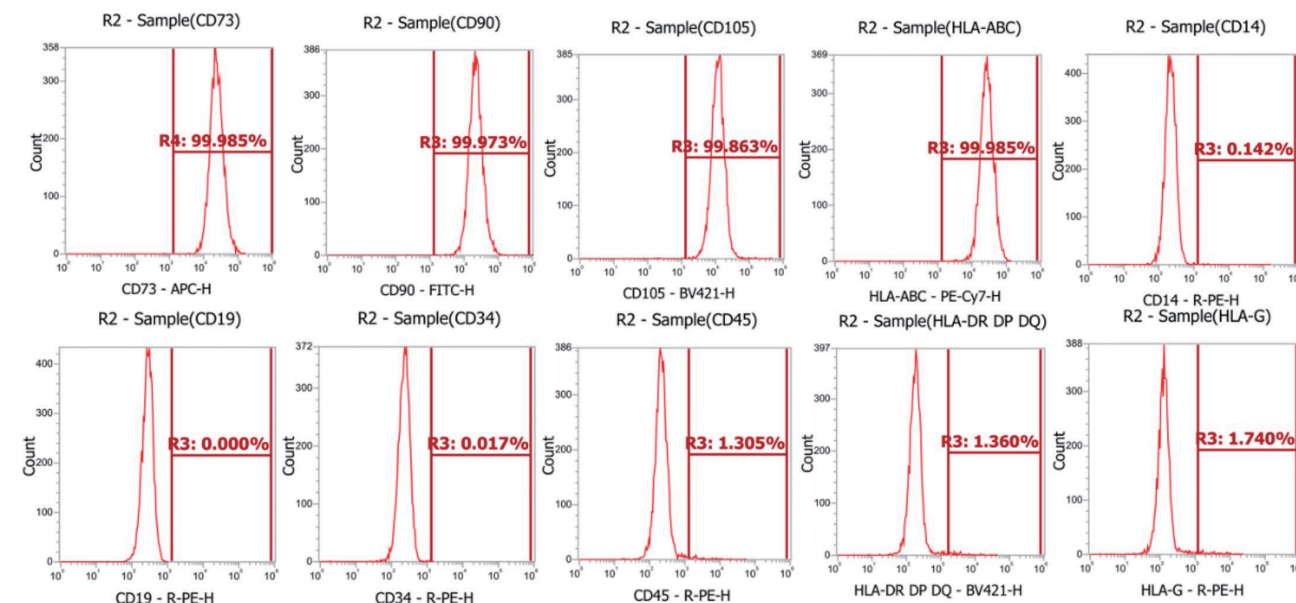


Giemsa Staining for Morphological Identification of UC-MSCs

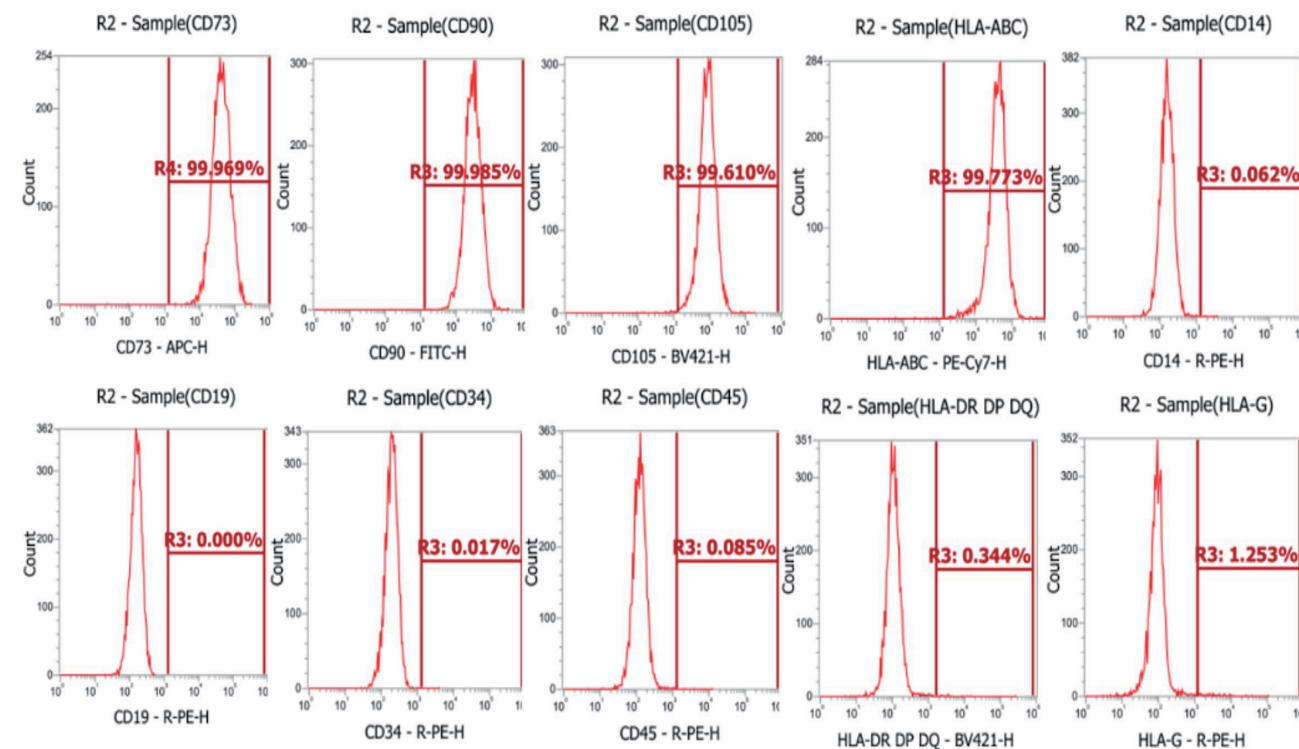


StarMedium® MSC

Chemically Defined Medium for Mesenchymal Stem Cells
Maintains Surface Marker Expression of UC-MSCs Across Multiple Passages

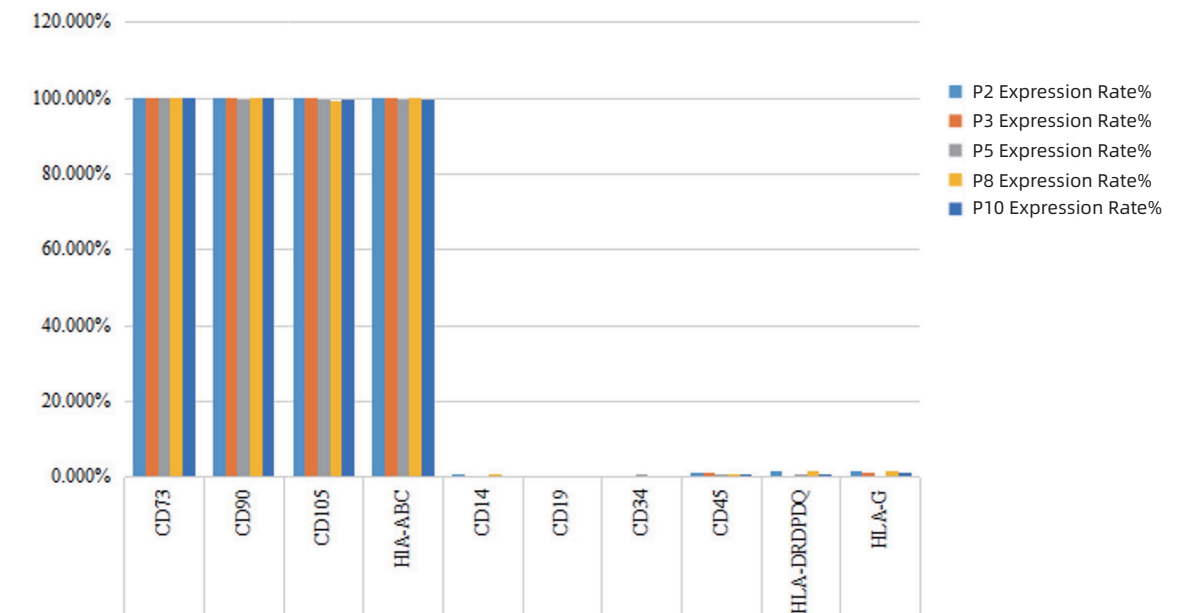


Detection of Characteristic Surface Markers in P2-Generation UC-MSCs



Detection of Characteristic Surface Markers in P10-Generation UC-MSCs

Detection Results of UC-MSC Surface Markers

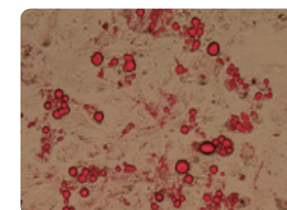
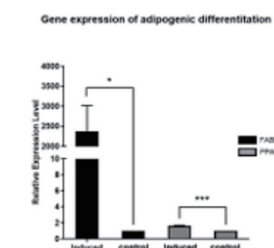


Detection of Expression Rates of Characteristic Surface Markers in UC-MSCs

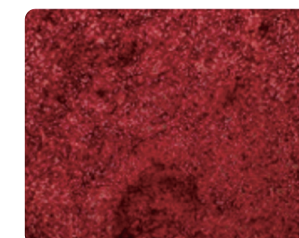
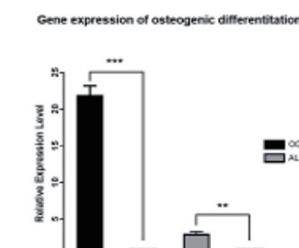
StarMedium® MSC

Mesenchymal Stem Cell Chemically Defined Medium Can Well Maintain the Adipogenic, Osteogenic, and Chondrogenic Differentiation Capabilities of MSCs

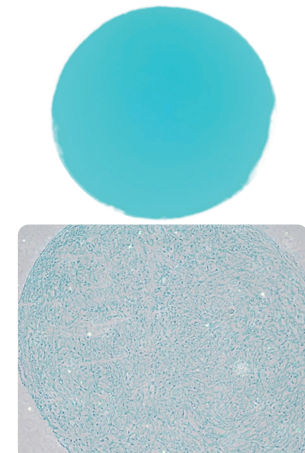
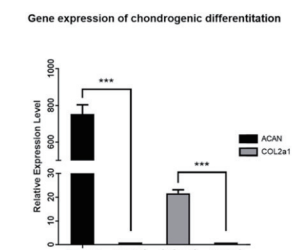
A Adipogenic Differentiation Assay



B Osteogenic Differentiation Assay

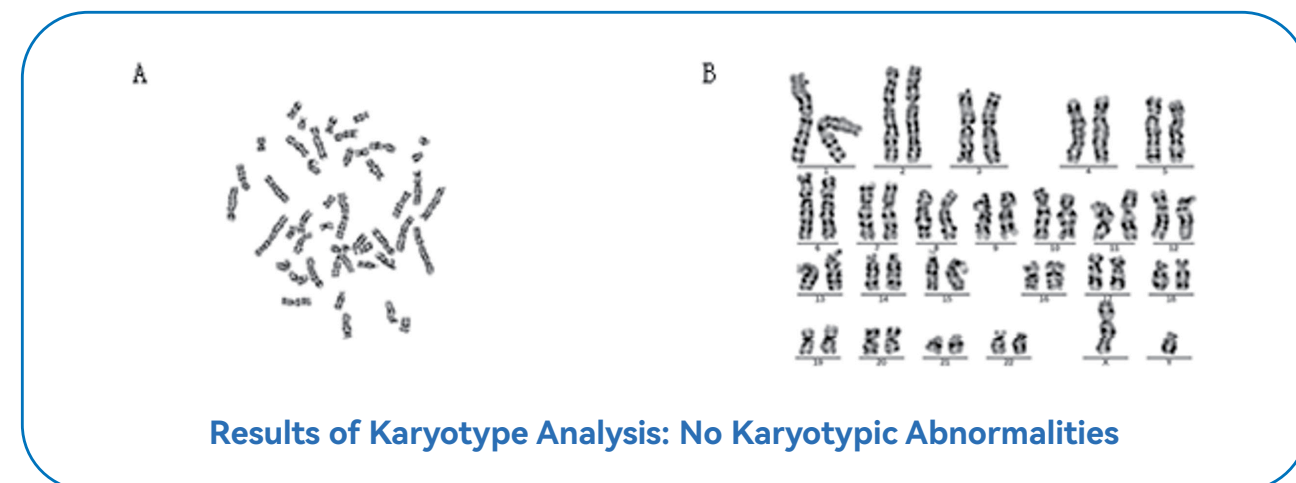
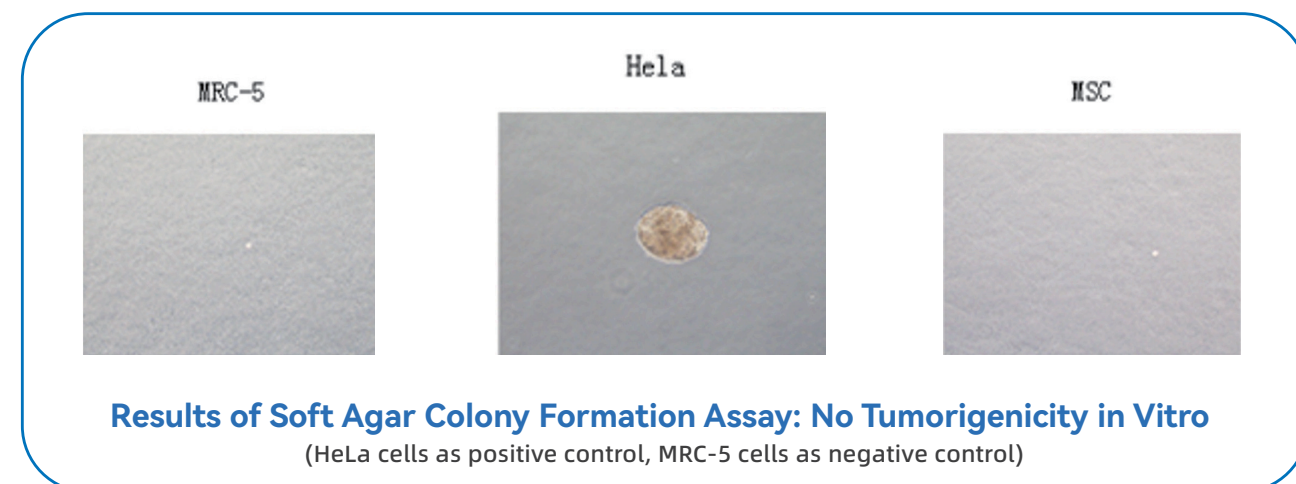
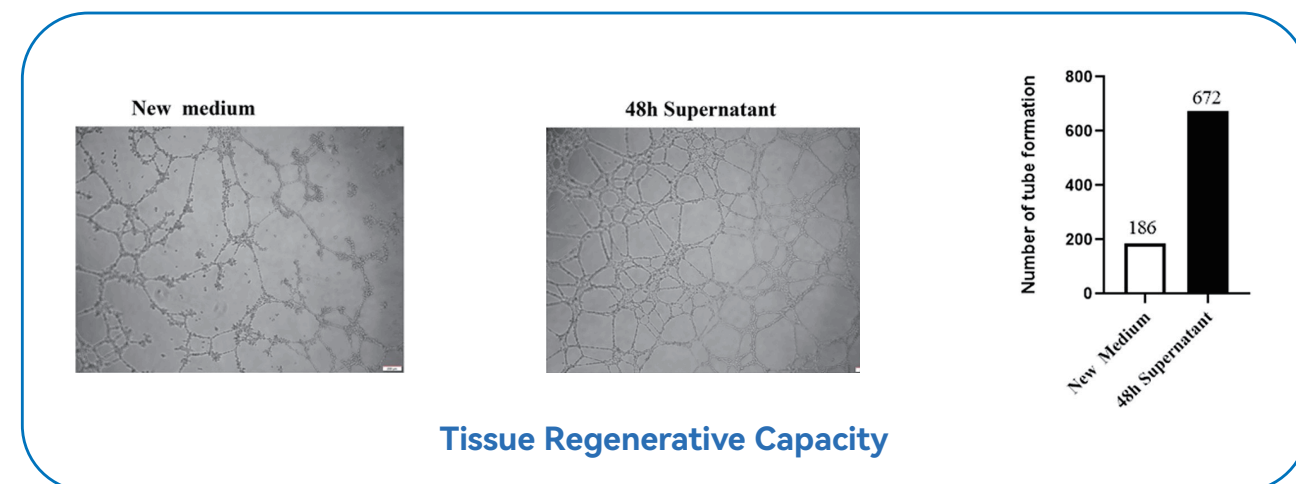


C Chondrogenic Differentiation Assay



StarMedium® MSC

Mesenchymal Stem Cells (MSCs) Cultured in Chemically Defined Medium for MSCs Possess Tissue Regenerative Capacity and High Clinical Safety



DMF Registration Number: 041792

3mL 添加物

FDA U.S. FOOD & DRUG ADMINISTRATION

DMF 041792

DMF ACKNOWLEDGEMENT

SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
ATTENTION: ZHENHUA SUN, GENERAL MANAGER
UNIT 504-1, BUILDING A3, 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: 041792
DATE OF SUBMISSION: APRIL 29, 2025
DMF TYPE: II
SUBJECT (TITLE): CHEMICALLY DEFINED MEDIUM FOR MESENCHYMAL STEM CELLS
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.

Huachen Bio: Core Technology Platforms

Culture Medium Development Platform

- Component Screening Procedure for Chemically Defined (CD) Medium
- Optimization and Simulation Procedure for Stem Cell Culture on 3D Microcarriers
- Integrated Intelligent Manufacturing System Management Platform for Cells

Independent Intellectual Property Rights Core Technology Platforms

Overall Solution

10 Billion-Scale Culture Process of Stem Cells Using 3D Microcarriers
100 Billion-Scale Culture Process of NK Cells

Ordering Information

Kit Name	Product Cat#	Specs	Remarks
StarMedium Chemically Defined Medium For Mesenchymal Stem cell(With Phenol Red)	HC-CD03R	500ml/bottle	①Serum-free, animal-derived component-free, platelet lysate-free, truly serum-free; ②Suitable for primary and passage culture; ③Human-derived component-free, containing recombinant human serum albumin ; ④Chemically defined composition, high batch-to-batch consistency; ⑤High performance, efficiently promoting MSC expansion; ⑥Manufactured in compliance with GMP standards, supporting clinical-grade/pharmaceutical-grade cell culture; ⑦3ml additive volume, low protein content; ⑧Higher quality, endotoxin < 0.1 EU/mL
StarMedium Chemically Defined Medium For Mesenchymal Stem cell(Without Phenol Red)	HC-CD03F	500ml/bottle	
StarMedium Medium Supplement	HC-CD03S	3ml/bottle	

Product Catalog

NK Kit

Kit02 Enhanced Version
hyperClone® Human Cryopreserved Mononuclear Cells NK Activation/Expansion Kit



kit03 hyper Version
hyperClone® Human Fresh Blood NK Activation/Expansion Kit



kit05 Enhanced Version
hyperClone® Human Fresh Blood NK Activation/Expansion Kit



Kit09
hyperClone® NK Cells Seed Bank Resuscitation/Activation Kit



Cryopreservation Medium



Serum-free Cell Freezing Medium for PBMC/CBMC Cryopreservation



Serum-free Cell Freezing Medium for NK Cell Seed Bank



Serum-free Cell Freezing Medium



DMSO-free Cell Freezing Medium

PureSep-NK



γDT Kit

hyperClone® Human γDT Activation/Expansion Kit

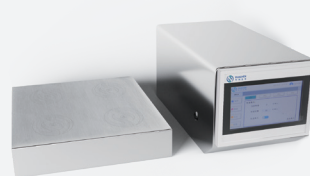


Microcarrier

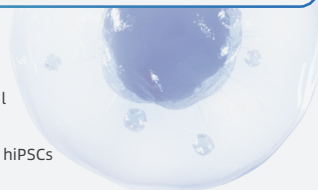
3D StarPore™ Microcarrier



StarSpan 4-Channel Mini Bioreactor



StarPluri™ Basal Medium
Chemically Defined Animal Component-Free, Feeder-Free Medium for Maintenance of hESCs and hiPSCs



Stem cell culture medium

HUACHEN

basal medium

Fibroblast Culture Medium

novaT-15
Chemically Defined Serum-Free Medium For Culture of Human Lymphocytes

novaNK-20
Chemically Defined Serum-Free Medium For Culture of Human Natural Killer cells

- ◆ 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: >2×10⁷ cells;
Cell yield per 10-layer cell factory: 8-10×10⁶ 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



novastem-MSC®

间充质干细胞无血清培养基

Serum-Free Medium For Mesenchymal Stem Cell

- ◆ Serum-free, platelet lysate-free
- ◆ Animal-derived component-free
- ◆ Human-derived component-free, containing recombinant human serum albumin (rHSA)
- ◆ Chemically defined, with high batch-to-batch consistency
- ◆ High efficiency, supporting primary and subculture of MSCs
- ◆ Manufactured in compliance with GMP standards, supporting pharmaceutical registration
- ◆ Higher quality, with endotoxin < 0.1 EU/ml



StarMedium®

新一代间充质干细胞化学成分限定培养基

Chemically Defined Medium For Mesenchymal Stem cell

Product Catalog

- ◆ High expansion fold: >100,000-fold expansion by Day 28
- ◆ High cell quantity: approximately 200 billion cells by Day 21
- ◆ High purity: >98% CD3⁺CD56⁺ (High-Efficiency Version), >90% CD3⁺CD56⁺ (Enhanced Version), and >90% CD16⁺CD56⁺
- ◆ High cell viability: >90% viability
- ◆ Allogeneic use: CD3⁺ cells < 1%, meeting the requirement for allogeneic application
- ◆ Low cost: The production cost per NK cell preparation is 1/3 to 1/5 of the original cost
- ◆ Pure factor: feeder-free, GMP-manufactured, with DMF filing number



hyperClone® NK KIT

人NK细胞高效扩增试剂盒

hyperClone Human NK Activation/Expansion Cocktail

- ◆ Gelatin-based composition with flexible porous structure design
- ◆ Particle size ranging from 200 μm to 350 μm
- ◆ All raw materials are derived from pharmaceutical excipients produced in compliance with GMP standards
- ◆ Irradiated and sterilized, ready for direct use
- ◆ Suitable for a variety of adherent cells



3D StarPore® Max

第二代Max微载体

3D StarPore gelatin dissolvable porous microcarrier for cell culture