

臨床等級細胞製劑起始原料-脂肪間質幹細胞

Clinical-Grade Stem Cell as Starting Material (Drug Substance)

Human Adipose-Derived Stem Cells

幹細胞株作為產品開發起始原料，可被拿來應用於再生醫療產品開發、基因載體研究、藥物篩選等領域。幹細胞株經過嚴格把關，包含：具捐贈者來源合適性檢測、IRB 核准文件、捐贈者與細胞株之外源病毒檢驗與臨床級場域製造(PIC/S GMP-Compliant Facility)，此外，該細胞株具備申請臨床經驗，能幫助客戶產品開發時排除倫理、安全性、臨床申請等疑慮。

國璽優勢 Why Choose GWOXI ?



- **PIC/S GMP 製劑廠**
PIC/S GMP-Compliant Facility
- 細胞來源符合捐贈者合適性判定
Donor Tissue Eligibility Assessment
- **IRB 核准文件 (含捐贈者同意書)**
Institutional Review Board (IRB)-Approved Documents



- 建置主細胞庫與工作細胞庫
Master Cell Bank and Working Cell Bank Establishment
- 細胞使用生物資源分讓庫建立
Stem Cell Line Available for Use as Drug Substance (DS)



- **USFDA DMF (含冷鏈運送)**
USFDA Drug Master File (Including Cold-Chain Logistics)
- 提供臨床級/研究級幹細胞株
Clinical-Grade / Research-Grade Stem Cell Lines Available
- 幹細胞株具國內外臨床試驗申請經驗
Experienced in Domestic and International Clinical Trials

細胞株品質管控 Quality Control Testing

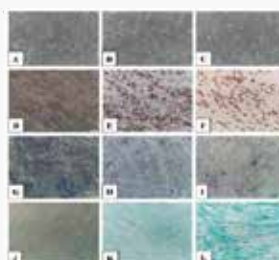
間質幹細胞報告
Certificate of Analysis
(COA)



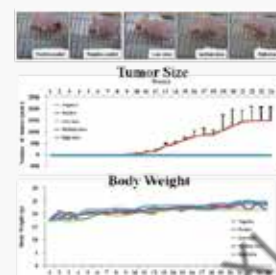
基因穩定
Genetic Stability
Testing



三分化能力
Tri-Lineage Differentiation
Potential



無致癌性
Tumorigenicity Assay



申請流程 Application Procedure

申請單填寫
Fill Application Form



評估
Assessment



研究級
Research Grade

臨床級
Clinical Grade



提供報價單
Quotation



出貨
Shipping



需求討論
Discussion



簽署合約
Sign Agreement

產品資訊 Product Information

	GX-hADSCs-RD 研究級細胞株 (Research Grade)	GX-hADSCs-CT 臨床級細胞株 (Clinical Grade)
捐贈者合適性判定 Donor Eligibility	○	○
IRB 核准 IRB Approved	○	○
USFDA DMF 範圍 Drug Master File		○
PIC/S GMP 場域製造		○
外源病毒檢測 Viral Testing		○
致瘤性檢測 Tumorigenicity Assay		○
細胞活性/型態 Cell Viability/Morphology	○	○
三分化測試 Tri-Lineage Differentiation Potential	○	○
細胞表面抗原檢測 hMSC Surface Marker Expression	○	○
核型分析 Karyotyping Testing	○	○
無菌/內毒素/黴漿菌 Sterility/Endotoxin/Mycoplasma Testing	○	○

應用經驗 Application Experience

幹細胞臨床應用 (Clinical Trials)

膝關節炎 (Knee Osteoarthritis)

臨床試驗階段 (Status) : Phase I/II (NCT03943576)

Chen CF, Chen YC, Fu YS, et al. Safety and Tolerability of Intra-Articular Injection of Adipose-Derived Mesenchymal Stem Cells GXPC1 in 11 Subjects With Knee Osteoarthritis: A Nonrandomized Pilot Study Without a Control Arm. Cell Transplant. 2024;33:9636897231221882.doi:10.1177/09636897231221882

糖尿病 (Diabetes)

臨床試驗階段 (Status) : Phase I (NCT05308836)

再生醫療產品應用 (Regenerative Products)

化妝品原料 (Cosmetic Use)

Human Adipose Derived Mesenchymal Stem Cell Exosomes - INCI name (Mono ID: 37487)

次世代產品開發 (Next Generation Products)

- Liang RY, Zhang KL, Chuang MH, et al. A One-Step, Monolayer Culture and Chemical-Based Approach to Generate Insulin-Producing Cells From Human Adipose-Derived Stem Cells to Mitigate Hyperglycemia in STZ-Induced Diabetic Rats. Cell Transplant. 2022;31:9636897221106995. doi:10.1177/09636897221106995
- Tsai YC, Cheng TS, Liao HJ, et al. Mesenchymal Stem Cell Secreted-Extracellular Vesicles are Involved in Chondrocyte Production and Reduce Adipogenesis during Stem Cell Differentiation. Tissue Eng Regen Med. 2022;19(6):1295-1310. doi:10.1007/s13770-022-00490-0



如有興趣
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Application Form

