

amsbio



StemFit Purotein[®]

Recombinant Proteins

Animal-Free Recombinant Cytokines & Growth Factors

Basic Research & Clinical Applications

High purity & performance
Reliable lot-to-lot consistency
Ready-to-use frozen formulation
GMP compliant proteins available
Regulatory compliance for cell & gene therapy *

**Approved by Japanese PMDA- equivalent to FDA*

For use with

iMatrix-511 Recombinant
Laminin E8 Fragments

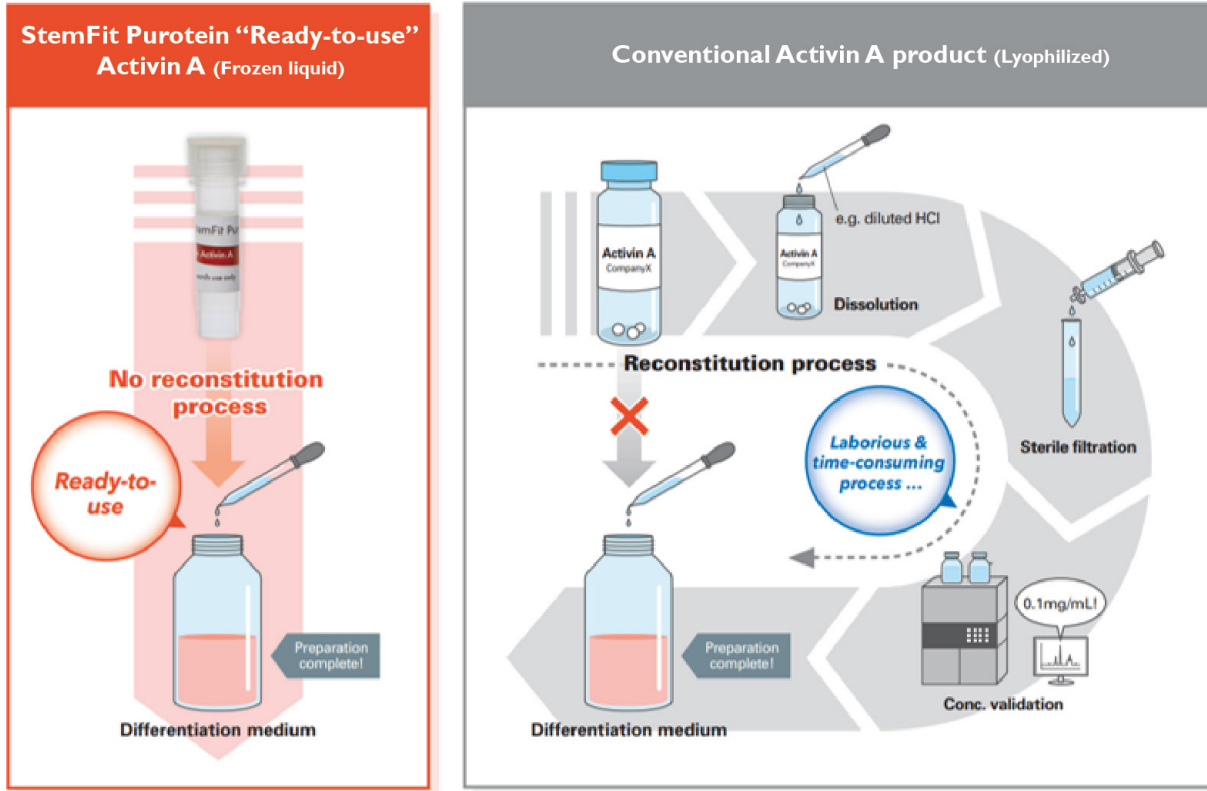
StemFit[®] Feeder-Free
Stem Cell Culture Media

STEM-CELLBANKER[®]
Cryopresarvation Media



READY-TO-USE FROZEN FORMAT

Conventional lyophilized products require reconstitution and concentration measurements which are time-consuming and introduce the risk of bacterial contamination or unexpected inactivation. StemFit Purotein recombinant protein are provided in a ready-to-use frozen liquid formulation, eliminating reconstitution steps. This feature simplifies the cell manufacturing process and accelerates cell therapy projects.



HIGH LOT-TO-LOT CONSISTENCY

Highly consistent and cost-effective *Corynebacterium glutamicum* expression system

Corynebacterium glutamicum is a gram-positive, non-sporulating soil bacterium which has successfully been used in the industrial production of amino acids for over 50 years. Since *C. glutamicum* secretes expressed target proteins into culture media, highly purified proteins can be obtained with a simple purification process. Additionally, gram-positive bacteria contribute low endotoxin products.

..... *Corynebacterium glutamicum*



<Features>

- Secretory expression system
- Low impurities
- Gram-positive, no endotoxin
- Long history for commercial production

Highly consistent and low-cost expression system

Cutting Edge Flow Microreactor (FMR) Refolding Technology (for Activin A)

Refolding is an important process in the production of recombinant proteins, since it has a significant impact on the product quality. Typically, a batch mixing process is used where denatured proteins and refolding buffer are mixed in a flask in a strictly controlled manner. Using this conventional method, it is difficult to efficiently mix sample and buffer in a reproducible manner, leading to inconsistent quality between batches.

StemFit Purotein recombinant Activin A is expressed in *E. coli* and manufactured with an advanced refolding technology, FMR (Flow Microreactor), in which protein and buffer are continuously flowed and mixed in micro space. FMR allows for the precise control and optimisation of the mixing reaction at a micro-second scale, enabling efficient and consistent refolding between lots and different manufacturing scales.

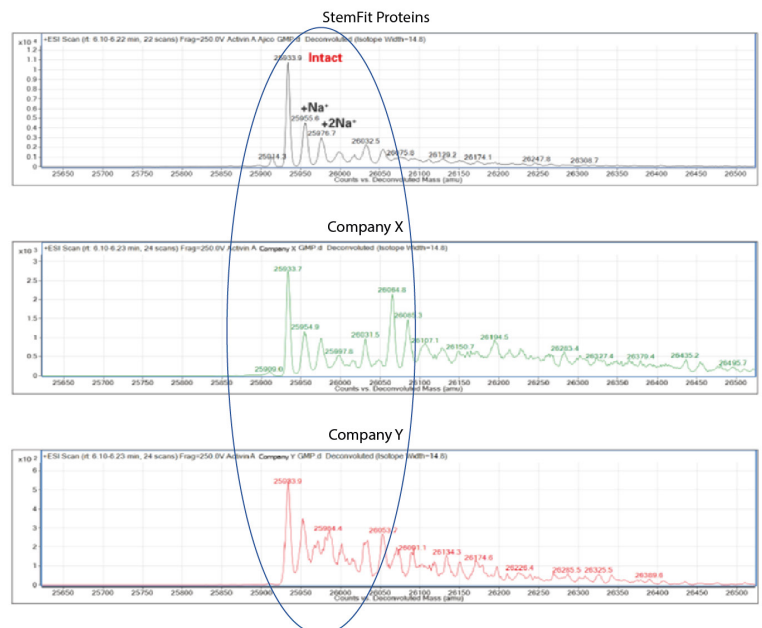
HIGH PURITY & HIGH PERFORMANCE

The secreting expression system of *C. glutamicum*, enables the omission of the refolding process. For other expression systems, a cutting-edge refolding technology, FMR, enables high purity and high-performance protein production. These highly purified proteins minimize undesirable effects from impurities and ensure consistent lot-to-lot results during manufacturing.

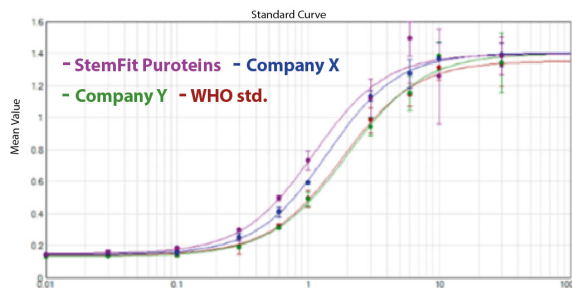
● SDS-PAGE



● Biological Activity



● Biological Activity



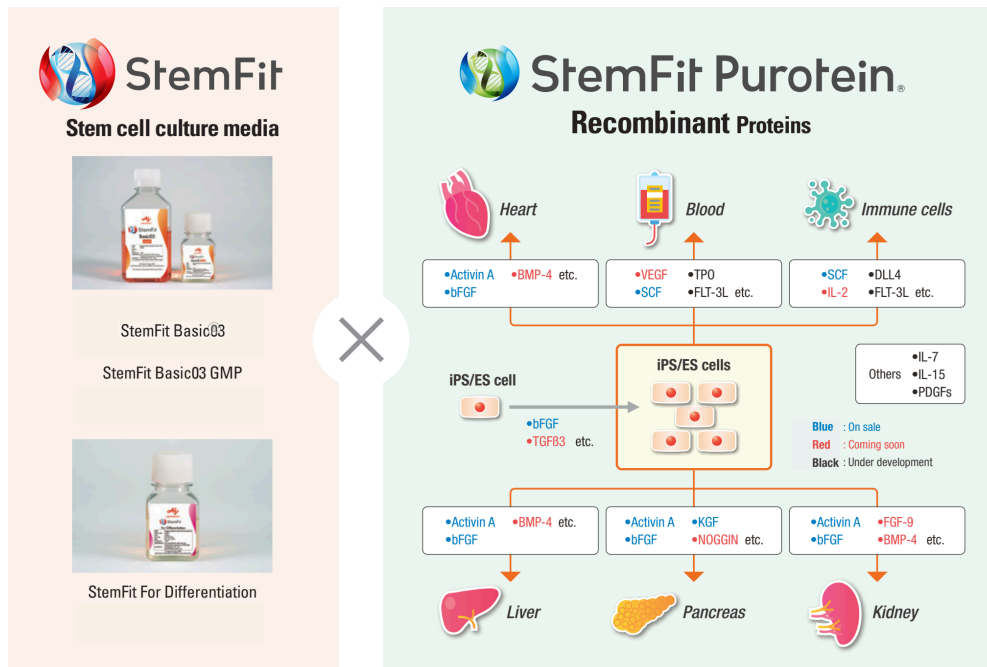
Activin A from various suppliers were tested

ANIMAL-ORIGIN FREE AND REGULATORY COMPLIANCE FOR CGT

Animal and human derived components are known to carry a risk of hazardous viral contamination for cell therapy. Therefore, StemFit Purotein is designed and manufactured under a strict animal-origin free policy and is free from animal and human derived components, according to the requirements of the Japanese PMDA (equivalent to the FDA) for ancillary materials. Additionally, StemFit Purotein offers GMP compliant products that are manufactured under GMP guidelines and are thus preferable for cell therapy product manufacturing.

HIGH COMPATIBILITY WITH STEMFIT HPSC CULTURE MEDIA AND IMATRIX ECM

Human pluripotent stem cells (hPSCs) are promising resources for research and cell therapy since they can differentiate into various types of cells. In the directed differentiation process of hPSCs, cells undergo several differentiation steps towards the target tissues. During this process, recombinant proteins are added to the culture media as growth factors to stimulate differentiation. StemFit hPSC media and iMatrix recombinant ECM are suitable for all stages of research and highly compatible with StemFit Purotein. The combination of StemFit hPSC media with StemFit Diff Differentiation Supplement and StemFit Purotein allows for the establishment of highly efficient differentiation systems in the laboratory while ensuring an easy transition to GMP-compliant production for future cell therapy manufacturing.



StemFit Purotein.

Product	Information	Packsize	Product code
Activin A	< Non-GMP > < GMP compliant >	10 ug (0.1 mg/ml)* 1 mg (0.1 mg/ml)	AMS-ACTA – 10 AMS-ACTA-1MG-GMP
SCF	< Non-GMP >	10 ug (0.1 mg/ml)*	AMS.SP-SCF-R-010UG
bFGF	< GMP compliant >	1 mg (0.3 mg/ml)	AMS-FGF-100
KGF	< Non-GMP >	10 ug (0.1 mg/ml)*	AMS.SP-KGF-R- 010UG
IL-2 (to be released 2022)	< Non-GMP >	3 mg (0.5 mg/ml)	TBC

*Larger packsizes available

AMSBIO | www.amsbio.com | info@amsbio.com

04/22

AMSBIO LLC
USA & Canada

1035 Cambridge Street,
Cambridge, MA 02141
T: +1 (617) 945-5033 or
T: +1 (800) 987-0985
F: +1 (617) 945-8218

AMSBIO Europe BV
EU

Berenkoog 41,
1822 BH Alkmaar,
Netherlands
T: +31 (0) 72 8080244
F: +31 (0) 72 8080142

AMS Biotechnology (Europe) Ltd
UK & Rest of the World

184 Park Drive, Milton Park
Abingdon OX14 4SE
T: +44 (0) 1235 828 200
F: +44 (0) 1235 820 482

AMS Biotechnology (Europe) Ltd
Switzerland

Via Lisano 3,
(CP.683)
CH-6900 Massagno
T: +41 (0) 91 604 55 22
F: +41 (0) 91 605 17 85

AMSBIO Europe BV
Deutschland

T: +49 (0) 69 779099
F: +49 (0) 69 13376880