

StemFit Purotein™

Recombinant Proteins



Activin A



SCF



KGF



BMP-4



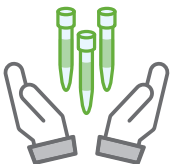
VEGF

As cell therapy development progresses, the demand for recombinant proteins is rapidly increasing. Specifically, recombinant proteins are required for manufacturing cell therapy products to ensure higher quality, consistency between lots, and compliance with various laws and regulations across the world.

StemFit Purotein™, produced by Ajinomoto, whose name comes from the combination Pure & Protein, is a brand of recombinant proteins designed for laboratory or GMP manufacturing of cell therapy products. To ensure sterile products, strict guidelines for manufacturing and quality testing are conducted.

All StemFit Purotein™ products are manufactured free from animal or human derived components, ensuring high safety and lot-to-lot consistency. Additionally, our highly efficient protein expression system and purification flow enables high purity and quality while maintaining affordable prices. Furthermore, the recombinant proteins are provided in a frozen liquid format enabling the omission of time-consuming reconstitution, making them perfect for advanced manufacturing.

— Product Features —



Affordable Price

We are committed to technological innovation, production at the optimal scale, and cost reduction, so that we can always supply products at an affordable price.



Animal Origin Free

Minimize the risk of viral contamination and lot-to-lot variation with an animal-origin-free formula.



Regulatory Compliant

Ability to produce and provide GMP compliant proteins enables the use for research and clinical cell therapy production.



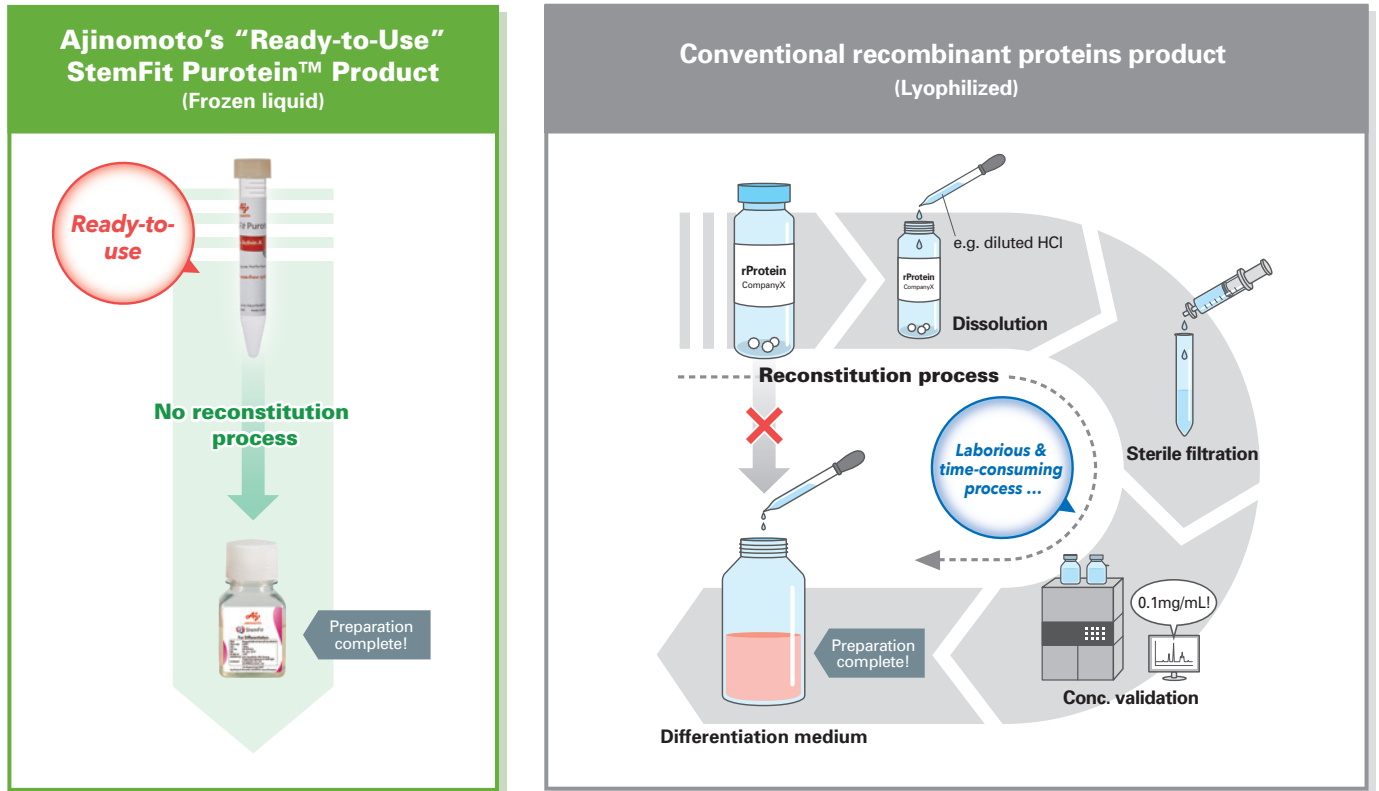
Ready-to-Use Format

Proteins are provided as a frozen liquid to eliminate the time consuming process of reconstitution, ensuring consistent results.

» Ready to Use Frozen Form

Conventional lyophilized products require reconstitution and concentration measurements which are time-consuming and introduce a risk of bacterial contamination or unexpected denaturation. StemFit Purotein™ products are provided in a frozen liquid form which is ready to use and could omit reconstitution steps. This feature simplifies the cell manufacturing process and accelerates cell therapy projects.

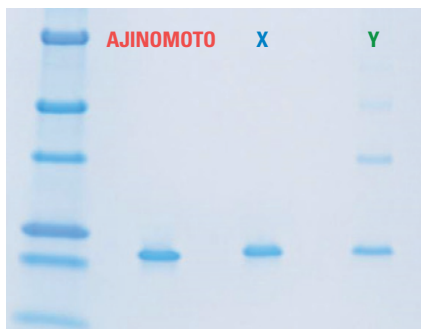
• Simplified Protocols without Reconstitution



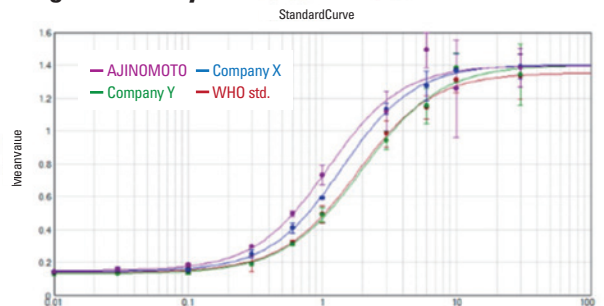
» High purity & High performance

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



» Animal-Origin Free & Regulatory Compliance for CGT

Animal or human derived components, such as serum derived albumin, or animal derived recombinant proteins, 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 or human derived components according to the requirement of Japanese PMDA for ancillary materials. Additionally, StemFit Purotein™ offers GMP compliant products that are manufactured under GMP guidelines making them preferable for cell therapy product manufacturing.

» High Lot-to-Lot Consistency

• Excellent Protein Expression with *C. Glutamicum*

..... *Corynebacterium Glutamicum*



<Features>

- Secretory expression system
- Low impurities
- Gram-Positive, no Endotoxin
- Long history for commercial production

Corynebacterium glutamicum is a Gram-positive, non-sporulating soil bacterium which has successfully been used for industrial production of amino acids for more than 50 years. Using a simple purification process, secreted target proteins ideal for cell culture media can be extracted. Additionally, gram-positive bacteria contribute to low endotoxins in products.

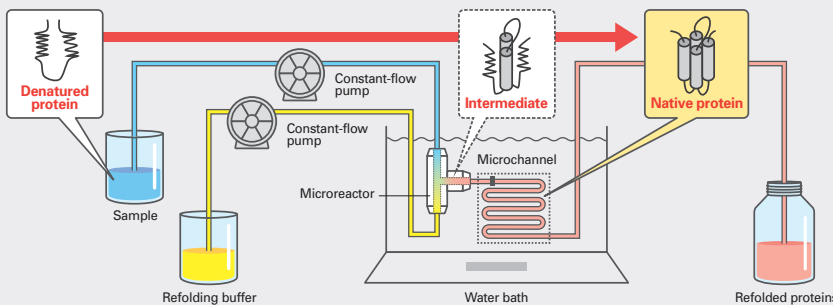
• Cutting Edge Refolding Technology (FMR)

Refolding has a significant impact on protein quality making it an important process in the production of recombinant proteins. During refolding, denatured protein and buffer are mixed in a flask in a strictly controlled manner. Some of StemFit Purotein™ products are manufactured with an advanced refolding technology, FMR (Flow Microreactor), in which protein and buffer are continuously flowed and mixed in a micro space. FMR allows us to precisely control and optimize the mixing reaction at a micro-second scale, enabling efficient and consistent refolding between lots and different manufacturing scales.

What is FMR?

Flow microreactor (FMR) is a flow reactor in which specific phenomena occur in micro space.

➔ Applying FMR to the refolding process leads to the production of high-purity proteins with reliable lot-to-lot consistency.



Characteristics	Advantages in Protein Refolding
• Fast mixing	High Productivity Stable Quality
• Control of reaction time	Higher Yield
• Flexibility of production scale	High Scalability

Difference from Conventional Refolding Technology

Conventional method (Batch mixing)

It is difficult to efficiently mix in a reproducible manner

Sample: Cytokine X

Leading to inconsistent quality between batches

FMR Method

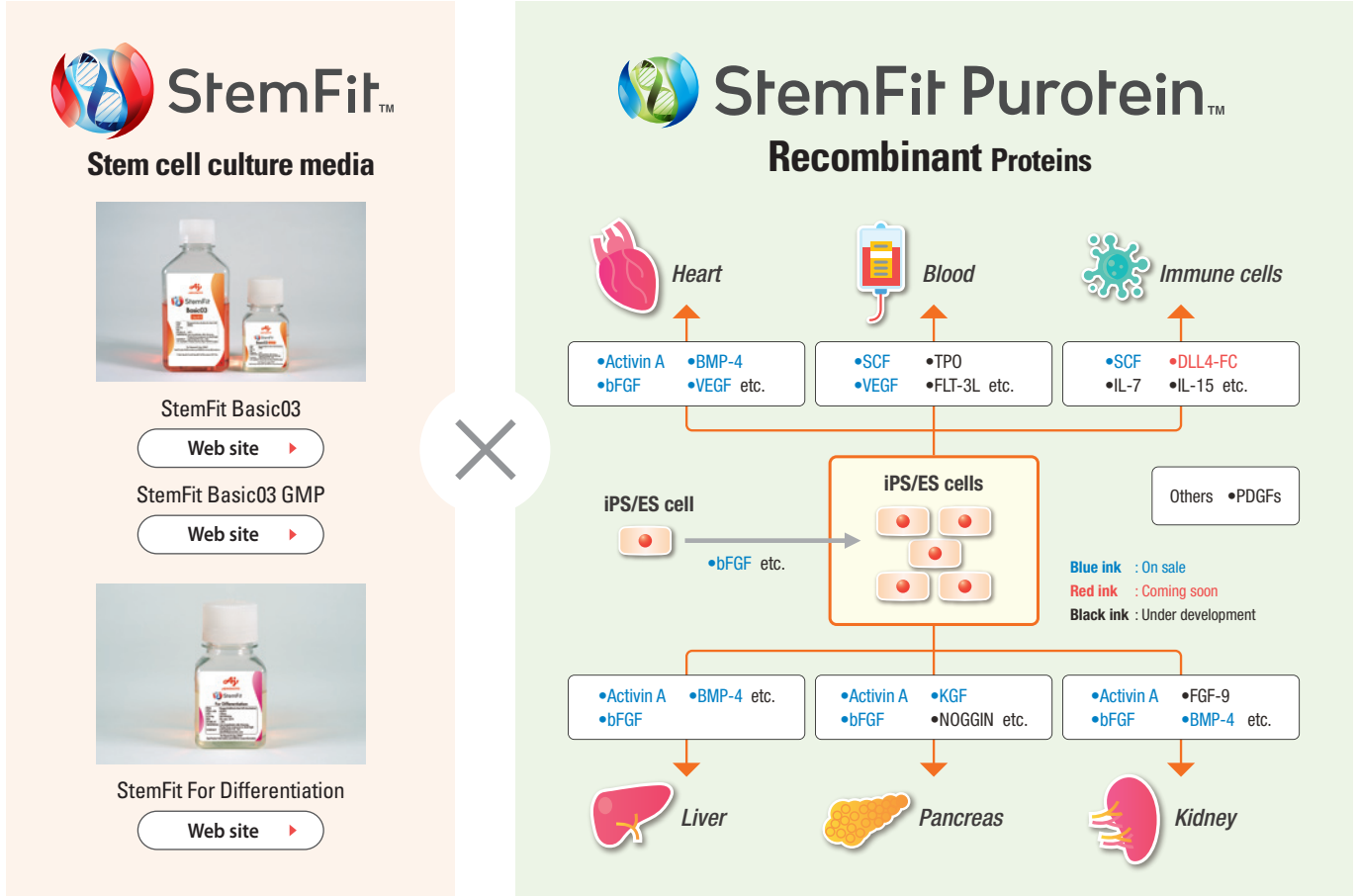
Enables the precise control of mixing in a scalable manner

Sample: Cytokine X

Resulting in a stable quality at any batch size

» High Compatibility with StemFit hPSC Culture Media

Human pluripotent stem cells (hPSC) are a promising resource for research and cell therapy due to their ability to differentiate into various type 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 into the culture media as growth factors to stimulate differentiation. StemFit hPSC media is a brand of hPSC media suitable for all stages of research. It is also highly compatible with StemFit Purotein™. The combination of StemFit hPSC media 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.



» Product list

Request pricing! ▶



Product	Information	
Activin A	10 µg, 50 µg, 1mg (0.1 mg/ml), GMP product available	Web site ▶
SCF	10 µg, 50 µg, 1mg (0.1 mg/ml)	Web site ▶
KGF	10 µg, 50 µg, 1mg (0.1 mg/ml), GMP product available	Web site ▶
VEGF	10 µg, 50 µg, 1mg (0.1 mg/ml)	Web site ▶
BMP-4	10 µg, 50 µg, 1mg (0.1 mg/ml)	Web site ▶

Eat Well, Live Well.



AJINOMOTO HEALTH & NUTRITION NORTH AMERICA, INC.

4020 Ajinomoto Dr, Raleigh, NC, USA 27610

<Contact> **REGENERATIVE MEDICINE DEPARTMENT** Mail : stemfit@ajiusa.com

