



StemFit Purotein®

Recombinant Proteins



Activin A

(Non-GMP, GMP compliant)



SCF

(Non-GMP)



KGF

(Non-GMP)



bFGF

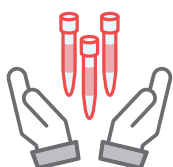
(GMP compliant)

As cell therapy development continues, the demand for recombinant proteins, such as growth factors and cytokines, is rapidly increasing for industrial use. In particular, recombinant proteins that are used in the manufacture of cell therapy products are required to have higher quality standards than conventional research reagents. This includes consistency between lots, and compliance with various laws and regulations.

StemFit Purotein®, whose name comes from Pure & Protein, is a brand of recombinant proteins applicable for use from the laboratory to GMP compliant manufacturing of cell therapy products.

All StemFit Purotein® products are manufactured free from animal or human derived components, which ensures 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, its frozen liquid form is a perfect match for advanced manufacturing because it enables the omission of the time-consuming reconstitution process.

— 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 risk of virus contamination and lot-to-lot variation with animal-origin free formula.



Regulatory compliance for cell therapy products

The PMDA has officially confirmed our product's eligibility for use in clinical cell therapy production (in Japan)



Frozen form that is "ready-to-use"

Can eliminate the time-consuming process of reconstitution, while ensuring consistent results.

» High lot-to-lot consistency

• Excellent Protein Expression System with *C. glutamicum*

..... *Corynebacterium glutamicum*



<Features>

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

Highly consistent and low-cost expression system

Corynebacterium glutamicum is a gram-positive, non-sporulating soil bacterium which has successfully been used for the industrial production of amino acids for more than 50 years.

Since *C. glutamicum* secretes expressed target protein into culture media, highly purified proteins can be obtained with a simple purification process. Additionally, gram-positive bacteria contribute low endotoxin products.

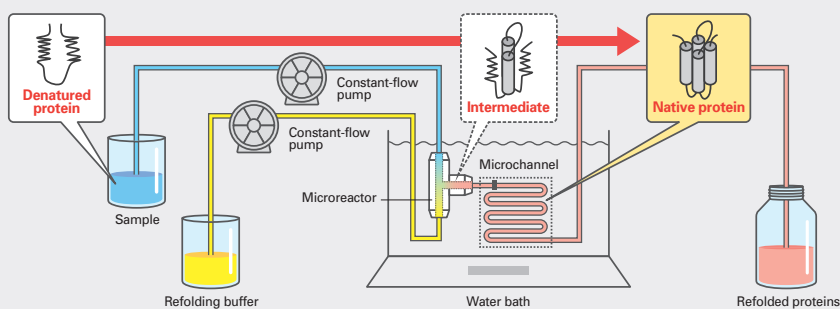
• Cutting Edge Refolding Technology, FMR

Refolding is an important process in the production of recombinant proteins since it has a significant impact on the product quality. In the process, denatured protein and a refolding buffer are mixed in a flask in a strictly controlled manner. StemFit Purotein® is 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, which enables efficient and consistent refolding between lots and different manufacturing scales.

What is FMR?

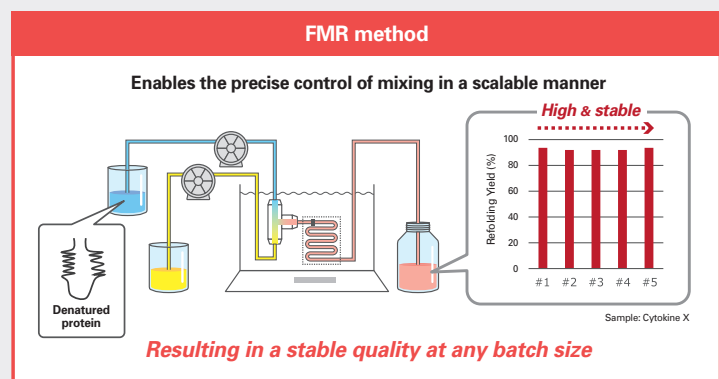
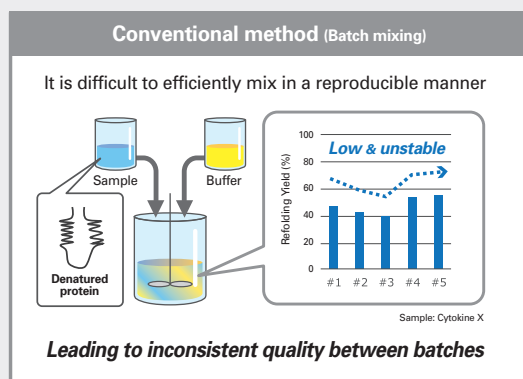
Flow microreactor (FMR) is a flow reactor in which specific phenomena occur in micro space.

➔ **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, Higher yield
• Precise control of reaction time	
• Flexibility of production scale	High scalability

Difference from conventional refolding technology



Patent pending (WO2020095894)

» Animal-Origin Free & Regulatory Compliance for CGT

Animal or human derived components, such as serum derived albumin, or animal cell 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 and are thus preferable for cell therapy product manufacturing.

» High purity & High performance

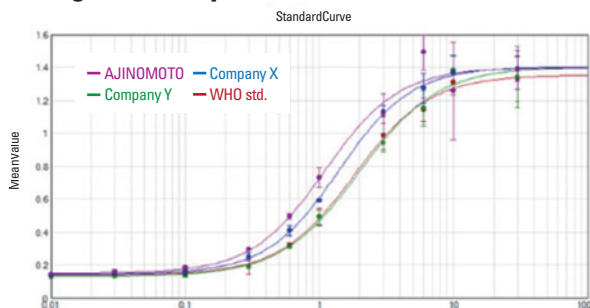
The secreting expression system of *C. glutamicum* enables the omission of the refolding process. For other expression systems, a cutting-edge refolding technology, FMR, enables high purity and high-performance protein production.

These highly purified proteins minimize undesirable effects from impurities and ensure consistent lot-to-lot results during manufacturing.

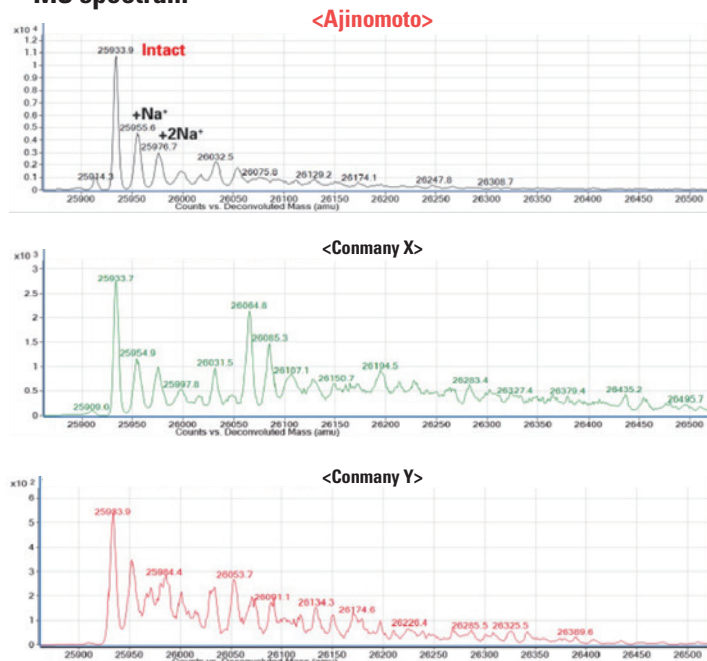
• SDS-PAGE



• Biological activity



• MS spectrum

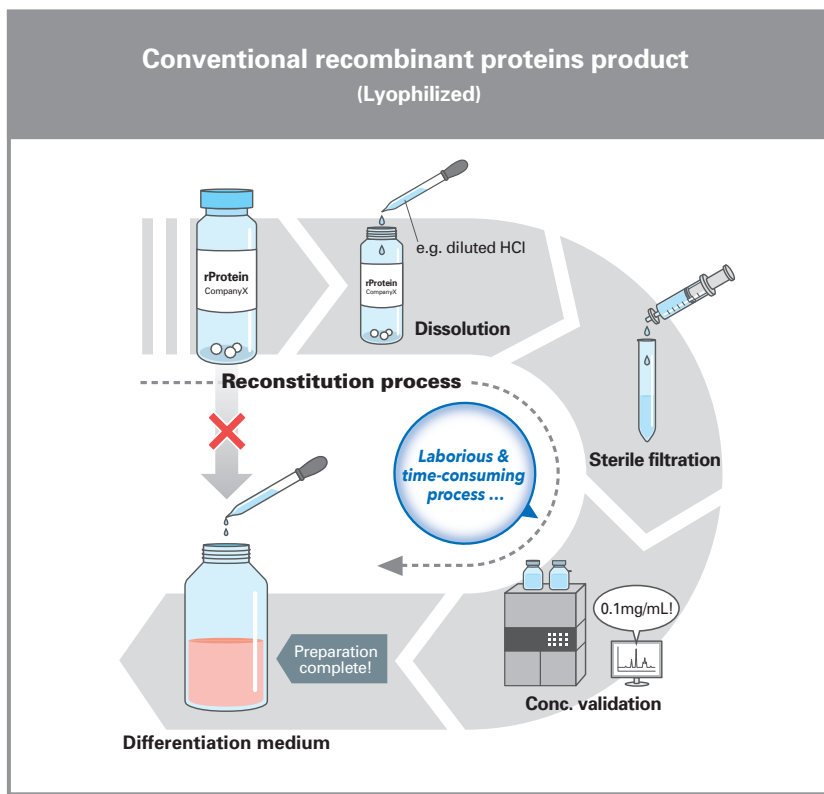
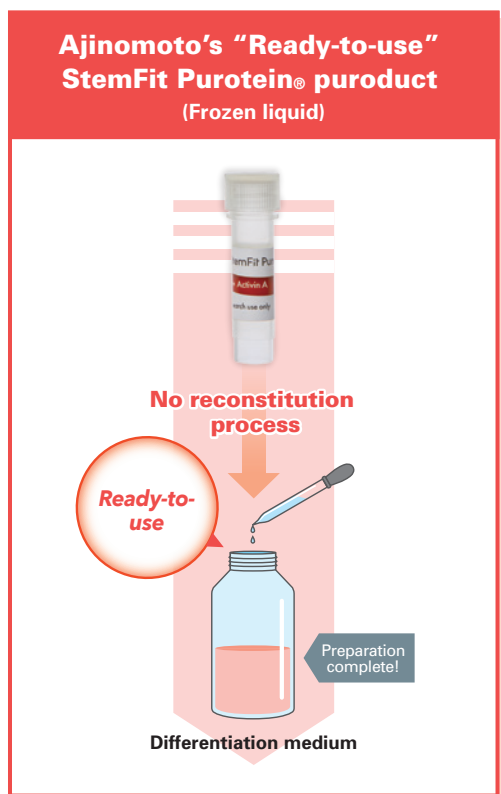


Activin A from various suppliers are tested.

» Frozen form, Ready to use

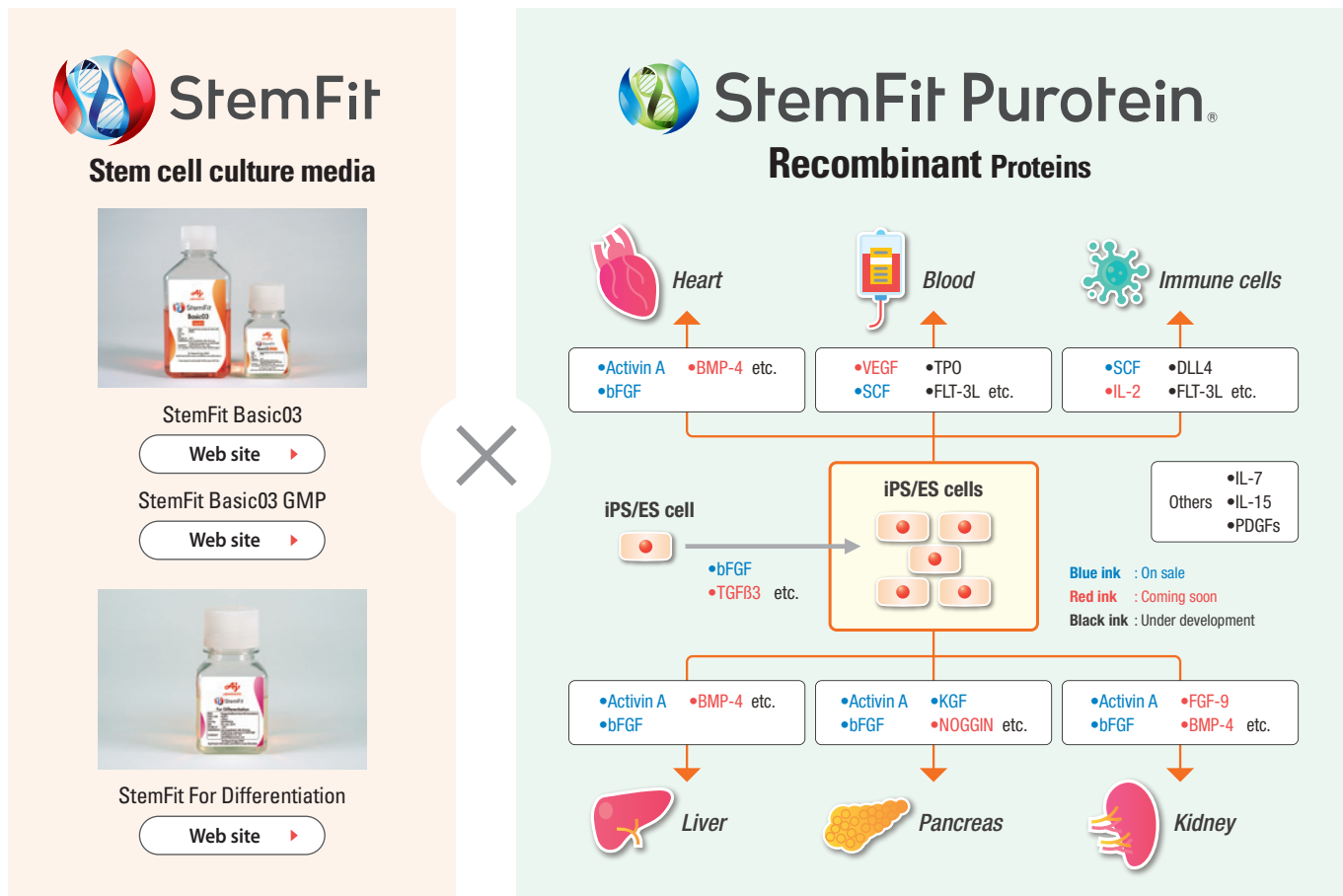
Conventional lyophilized products require reconstitution and concentration measurements which are time-consuming and introduce a risk of bacterial contamination or unexpected inactivation. StemFit Purotein® products are provided in a frozen liquid form which is ready to use and could omit reconstitution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

• Simplified protocols without reconstitution



» High compatibility with StemFit hPSC culture media

Human pluripotent stem cells (hPSC) are promising resources for research and cell therapy since they can 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

Please request pricing! ▶



Product	Information		
Activin A	<Non-GMP> <GMP compliant>	10μg, 50μg, 1mg(0.1mg/ml) 1mg(0.1mg/ml)	Web site ▶
SCF	<Non-GMP>	10μg, 50μg, 1mg(0.1mg/ml)	Web site ▶
bFGF	<GMP compliant>	1mg(0.3mg/ml)	Web site ▶
KGF	<Non-GMP>	10μg, 50μg, 1mg(0.1mg/ml)	Web site ▶
IL-2	To be released in 2022 <Non-GMP>	3mg(0.5mg/ml)	

Eat Well, Live Well.



AJINOMOTO CO., INC. 15-1 Kyobashi 1-chome, Chuo-ku, Tokyo 104-8315

〈Contact〉 **AJINOMOTO CO., INC.**

AminoScience Division, Business Strategy & Planning Dept.

Mail : stemfit@asv.ajinomoto.com

