

GMP Products for Therapeutics Manufacturing

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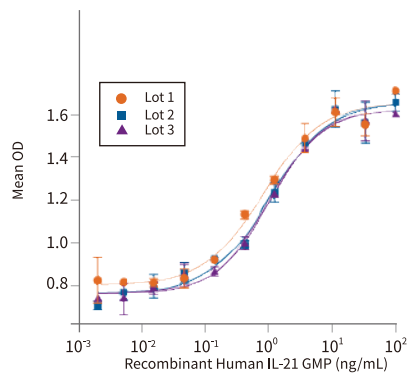
GMP Proteins

- ① Global 제약회사인 **GSK(GlaxoSmithKline)**에 **GMP Protein** 공급! (Since 2002)
- ② **Cell Therapy** 연구에 사용할 수 있도록 **USP Chapter <1043>**, **USP Chapter <92>**에 따라 만들어진 제품들!
- ③ **ISO9001, ISO13485**
- ④ 가장 많은 종류의 **GMP product** 보유!

Activin A	GDNF	IL-3†	KGF/FGF-7	SCF/c-kit Ligand†
BMP-2	GM-CSF†	IL-4†	LR3 IGF-I†	Shh N-Term†
BMP-4†	HGF	IL-6†	M-CSF†	Shh (C24II) N-Term†
EGF†	IFN-γ†	IL-7 †	Noggin	TGF-β1
FGF basic (145 aa)†	IGF-I†	IL-10†	Noggin Fc Tag	Thrombopoietin†
Flt-3 Ligand/FLT3L†	IL-1β†	IL-15 †	PDGF-AA†	TNF-α†
GDF-8/Myostatin	IL-2 †	IL-21†	PDGF-BB†	Wnt-3a

빨간색으로 표시된 protein들은 R&D에서만 출시되고 있는 GMP protein 입니다. † 표시된 protein들은 animal-free GMP protein 입니다

Lot-to-Lot Consistency



Lot-to-Lot Consistency는 GMP protein 선택에 가장 중요한 항목! R&D GMP Protein은 높은 lot-to-lot consistency를 보입니다

Certificate of Analysis Specifications

Test	Method	Specification	Result
Protein Mass	SDS-PAGE	13 kDa, reducing conditions	Pass
	Mass Spectrometry	The major peak by mass spectrometry is 15549 ± 23 Da with an allowed minor amount of 15418 ± 23 Da.	Pass
Protein Identity	N-terminal sequence analysis	Met-Ala ₂₁ -Pro-Thr-Ser-Ser-Ser-Thr-Lys-Lys	Pass
Activity	Measured in a cell proliferation assay using CTLL-2 mouse cytotoxic T cells. Gearing, A.J.H. and C.B. Bird (1987) in Lymphokines and Interferons, A Practical Approach. Clemens, M.J. et al. (eds): IRL Press. 295.	The ED ₅₀ for this effect is 0.05-0.25 ng/mL. The specific activity of recombinant human IL-2 is >5.0 x 10 ⁶ IU/mg, which is calibrated against the human IL-2 WHO International Standard (NIBSC code: 86/500).	0.139 ng/mL 10.4 x 10 ⁶ IU/mg 0.163 ng/mL (control) 8.8 x 10 ⁶ IU/mg (control)
Purity	SDS-PAGE	>97%, by SDS-PAGE with silver staining, under reducing conditions.	Pass
Host Cell Protein	ELISA	<0.5 ng per µg of protein when tested by ELISA.	Pass
Host Cell DNA	PCR	<0.0015 ng per µg of protein when tested by PCR.	Pass
Endotoxin Level	LAL method	<0.01 EU/µg, tested per USP<85> guidelines.	Pass
Mycoplasma	Ribosomal RNA hybridization assay	Negative	Pass
Sterility	Tested per USP <71> guidelines	No Growth	Pass

Lot# specific CoA 문서를 통해 protein mass부터 sterility까지, 실험 방법과 통과 기준, 통과 여부를 확인하실 수 있습니다.

GMP Small Molecules for Stem Cell Therapy

- The First GMP Small Molecules of the World
- Animal-Free Product
- Lot-to-Lot Consistent
- SB 431542/ Y-27632/ CHIR 99021/ XAV939

Tocris Product Quality Attributes

	Standard Catalog	Ancillary Material Grade	GMP
ISO 9001	○	○	○
QC Testing	○	○	○
Controlled Manufacturing Zone		○	○
ISO-7 Cleanroom		○	○
Endotoxin/Bioburden Testing		○	○
TSE and BSE Certification		○	○
Risk-based Approach to Manufacturing			○
ICH Q7			○

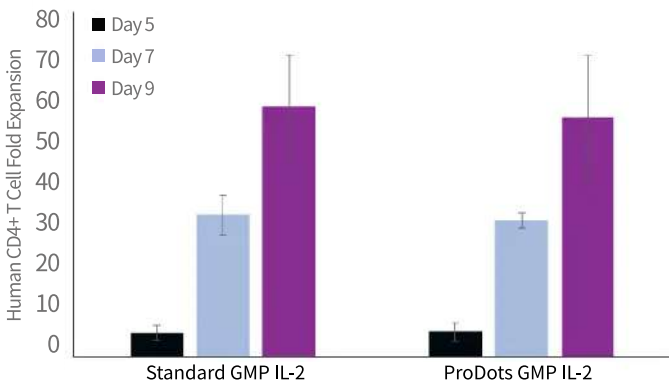
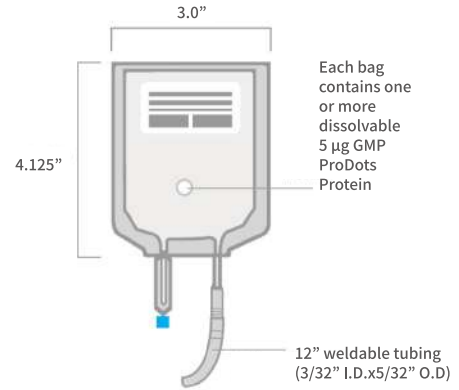
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GMP ProDots Protein in a BAG

- 신속 간편한 Reconstitution & Recovery
- 즉시 사용이 가능한 Dot form 형태
- R&D systems가 보장하는 High Purity
- 일반 GMP Protein과 상응하는 높은 Bioactivity
- USP<71> guideline을 따르는 package
- IL-2, IL-7, IL-15



R&D GMP IL-2와 ProDot GMP IL-2의 CD4+ T cell expansion level 비교 data.

두 제품의 activity가 거의 유사함을 알 수 있습니다.

	GMP ProDots in a bag Exact amount for process	Standard 1 mg vial protein Aliquot exact amount for process	Process Size 25 µg vial protein Use the entire vial or discard unused protein
Clean room time	🕒	🕒🕒🕒	🕒🕒
Optimal for culture performance	✓	✓	✗
Automatable and standardized	✓	✗	✓
Risk (handling/error)	👤	👤👤👤👤	👤👤
Cost (time/risk reduction)	\$\$	\$	\$\$\$\$

GMP Cloudz

Cloudz™ Cell Activation Kits

- Magnetic bead-free (no beads to remove) - 공정의 단순화
- Simple
- T Cell Activation Kit / Treg Expansion Kit

Beads-Free

