

# GMP Products for Therapeutics Manufacturing



## 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!

### GMP protein 종류

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

† 표시된 protein들은 animal-free GMP protein 입니다

### GMP vs. RUO 차이점

Test	GMP	RUO
Regulation of manufacturing	<ul style="list-style-type: none"> <li>• ISO 9001:2015, ISO 13485:2016-certified facility</li> <li>• USP Chapter &lt;1043&gt;, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products</li> <li>• Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products</li> <li>• USP Chapter &lt;71&gt;, Sterility testing guideline</li> </ul>	ISO 9001:2015, ISO 13485:2016
Animal-free	대부분	일부분
Drug Master File, Quality Management System	Yes	No
Traceability documentation (COO, COA, SDS, Insert)	Yes	Yes

### CoA contents GMP vs. RUO

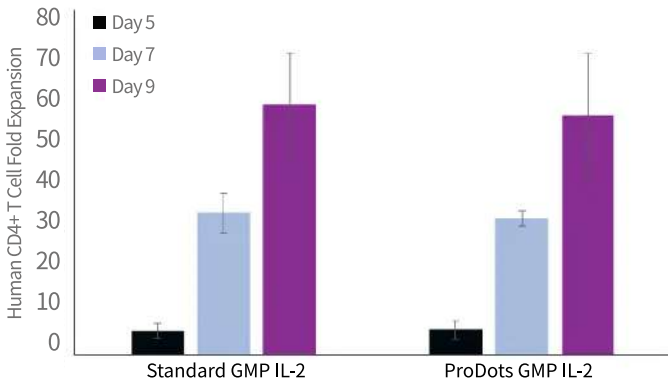
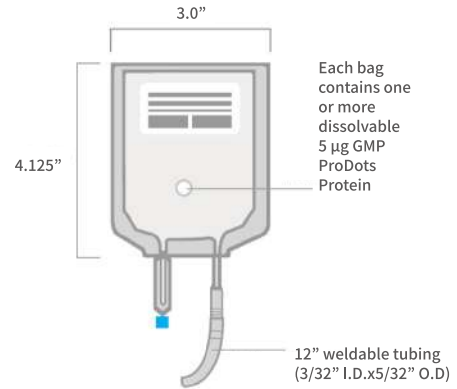
Test	GMP	RUO
Protein mass	SDS-PAGE, Mass spectrometry	SDS-PAGE
Protein identity	N-terminal 10 amino acid	N-terminal 1~3 amino acid
Activity	Cell based assay	Cell based assay
Purity	SDS-PAGE	SDS-PAGE
Endotoxin level	LAL method	LAL method
Host cell protein	ELISA	X
Host cell DNA	PCR	X
Mycoplasma	Ribosomal RNA hybridization assay	X
Sterility	Tested per USP <71> guidelines	X
결과값	모든 test에 대한 결과값 제공	X

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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 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			○