

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

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

GMP vs. RUO 차이점

| Test | GMP | RUO |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Regulation of manufacturing | <ul style="list-style-type: none"> • ISO 9001:2015, ISO 13485:2016-certified facility • USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products • USP Chapter <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing • Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products • USP Chapter <71>, Sterility testing guideline | 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

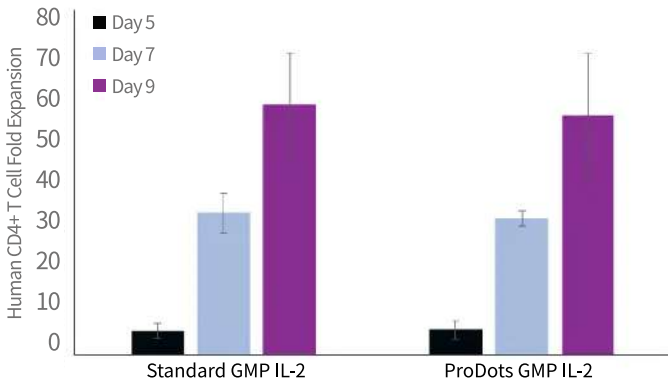
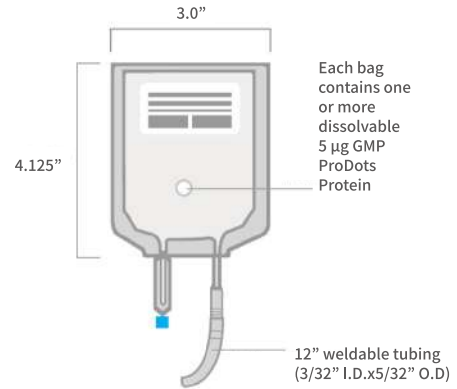
| Test | GMP | RUO |
|-------------------|-----------------------------------|---------------------------|
| Protein mass | SDS-PAGE, Mass spectrometry | SDS-PAGE |
| Protein identity | N-terminal 10 amino acid | N-terminal 1~3 amino acid |
| Activity | Cell based assay | Cell based assay |
| Purity | 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 | | | ○ |