# Biosimilar는 GMP와 함께합니다

## GMP (Good Manufacturing Practice)

- 우수의약품을 제조하기 위한 공장에 원료의
- 구입~출하까지의 기준 각국 마다 자체적인 GMP
- 가이드라인이 있으며 기준을 따르지 않은 경우 불이익 발생

* 생산단계 뿐만 아니라 연구단계에서도 GMP의 규정은 지켜져야 합니다.

| 연구개발·허가단계 | | | | | | | | 제조단계 | 사용단계 |
|---|---|---|---|---|---|---|---|---|---|
| 기초 조사 | 물질탐색 발견 이화학적 구조결정 스크리닝 | 비임상실험 | 제제화연구 | 임상시험 | | | 심사 허가 | 생산 | 판매 사용 |
| | | | | 1상 임상시험 | 2상 임상시험 | 3상 임상시험 | | | |
| | | | GLP | | GCP | | | GMP | |
| 임상시험 계획 승인 신청 | | | | 의약품 품목 허가 신청 | | | 신약 허가 | 재심사<br>재평가<br>허가외 사용 평가 | |

MFDS(식품의약품안전청)에서 제공하는 GMP 월간소식지를 통해 GMP 법령 개정안을 체크해보세요.

Click here ≫

# R&D systems GMP 제품에서 제공하는 제품 정보 항목들

R&D SYSTEMS a bio-techne brand

## Recombinant Human TGF-β1 GMP

Catalog Number: 240-GMP

| DESCRIPTION | |
|---|---|
| **Source** | Chinese Hamster Ovary cell line, CHO-derived human TGF-beta 1 protein<br>Ala279-Ser390<br>Accession # P01137<br>Manufactured and tested under cGMP guidelines. |
| **N-terminal Sequence Analysis** | Ala-Leu-Asp-Thr-Asn-Tyr-(Cys)-Phe-Ser-Ser |
| **Structure / Form** | Disulfide-linked homodimer |
| **Predicted Molecular Mass** | 12.8 kDa (monomer) |

| SPECIFICATIONS | |
|---|---|
| **SDS-PAGE** | 12 kDa, reducing conditions<br>24 kDa, non-reducing conditions |
| **Activity** | Measured by its ability to inhibit the IL-4-dependent proliferation of HT-2 mouse T cells. Tsang, M. *et al.* (1995) Cytokine **7**:389.<br>The $ED_{50}$ for this effect is 0.04-0.2 ng/mL.<br>The specific activity of recombinant human TGF-β1 GMP is approximately 2.5 x $10^4$ U/µg, which is calibrated against human TGF-β1 Standard (NIBSC code: 89/514). |
| **Endotoxin Level** | <0.10 EU per 1 µg of the protein by the LAL method. |
| **Purity** | >97%, by SDS-PAGE with silver staining. |
| **Host Cell Protein** | < 0.5 ng per µg of protein when tested by ELISA. |
| **Mycoplasma** | Negative when tested in a ribosomal RNA hybridization assay. |
| **Adventitious Virus** | Master Cell Bank tested for adventitious viruses |
| **Formulation** | Lyophilized from a 0.2 µm filtered solution in Acetonitrile and TFA. See Certificate of Analysis for details. |

| PREPARATION AND STORAGE | |
|---|---|
| **Reconstitution** | Reconstitute at 100 µg/mL in 4 mM HCl. |
| **Shipping** | The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below. |
| **Stability & Storage** | **Use a manual defrost freezer and avoid repeated freeze-thaw cycles.**<br>• A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.<br>• 1 month, 2 to 8 °C under sterile conditions after reconstitution.<br>• 3 months, ≤ -20 °C under sterile conditions after reconstitution. |

- Source information
- N-terminal sequencing of the first 10 amino acids
- Purity by SDS-PAGE and Mass Spectrometry
- Bioactivity testing calibrated to WHO International Standards
- Sterility testing to USP
- Endotoxin levels
- Certification and Regulatory Guidelines followed, including:
  - ▶ 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

주소 : ( 05854 ) 서울특별시 송파구 송파대로 201 테라타워2 A동 1113호 (문정동 642번지)

웅비메디텍
02.881.5432