(GMP 제품은 까다로운 절차 속에서 나오는 Good Manufacturing Product 입니다.)

# MFDS(식품의약품안전처)의 법령 최신 제, 개정고시등을 주기적으로 확인하세요

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## GMP Protein을 선택하는데에 있어 고려해야할 사항

- 1. Expect Suppliers to be knowledgeable and meet pertinent requirements
- 2. Consistency from lot-to-lot
- 3. Ability to scale
- 4. Secondary suppliers
- 5. Experience counts
- 6. Quality management systems

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### R&D systems의 GMP 'grade' Protein이 제공하는 Document List

R(I) SYSTEMS a biotechne brand

Description

**Recombinant Human** Sonic Hedgehog/Shh (S24II), N-Terminus **GMP** 

1845-GMP-025

Size: 25ug Lot: GAC70219021

### Certificate of Analysis

Source E. coli-derived human Sonic Hedgehog/Shh protei Cys24-Gly197 (Cys24lle-lle), with an N-terminal Met Accession # NP\_000184 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under current Good Manufacturing Practice (GMP) guidelines N-terminal Sequence Met-Ile-Ile-Gly<sub>25</sub>-Pro-Gly-Arg-Gly-Phe-Gly Predicted Molecular Mass 20 kDa Specifications SDS-PAGE 22 kDa, reducing conditions Activity Measured by its ability to induce alkaline phosphatase production by C3H10T1/2 mouse embryonic fibroblast cells. Nakamura, T. et al. (1997) Biochem. Biophys. Res. Commun. 237:465 The ED50 for this effect is 0.1-0.4 µg/mL. When this lot of rhSHH was assayed on 02/18/19, the ED50 was 0.278 µg/mL. The ED50 for the control lot was 0.345 µg/mL.

#### Purity >95% 1 µg/lane of the protein was resolved in SDS-PAGE with silver staining. This lot showed a single band at approximately 21 kDa under reducing condition <0.01 EU per 1 µg of the protein, determined by the LAL method. This lot had an endotoxin level of 0.00343 EU/µg of the protein. Endotoxin Level Host Cell Protein <0.5 ng per µg of protein when tested by ELISA Negative when tested in a ribosomal RNA hybridization assay Mycoplasma Mass Spec The calculated molecular mass for this product is 19814 Da. The result of mass spectrometry analysis for this lot was 19797 Da Bioburden rhShh was filtered through a 0.2 micron membrane and packaged under aseptic conditions. 25 µg of rhShh was plated on Blood Agai

## **Certificate of Analysis**

Size: 25µg Lot: GACZ0219021

### **Manufacturing Specifications**

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth actors and Cytokines Used in Cell Therapy Manufacturing.

### **Certificate of Analysis**

Size: 25µg Lot: GACZ0219021

### **Product Specific Notes**

END USER TERMS OF USE OF PRODUCT

The following terms are offered to you upon your acceptance of these End User Terms of Use of Product. By using this product, you indicate your acknowledgmen and agreement to these End User Terms of Use of Product. If you do not agree to be bound by and comply with all of the provisions of these End User Terms of Use of Product, you should contact your supplier of the product and make arrangements to return the product.

- 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 <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing

▶ USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products

▶ Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products