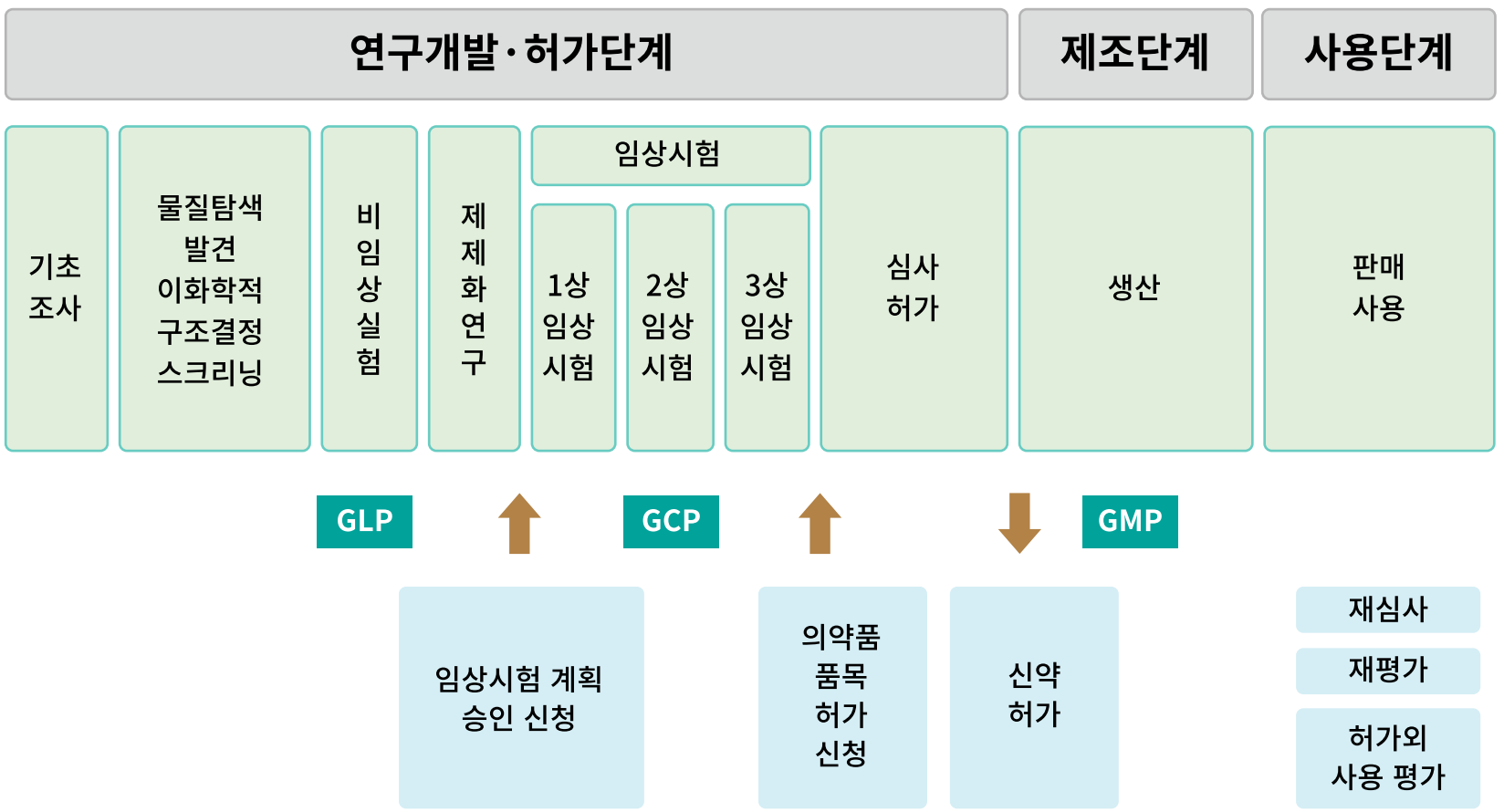

(GMP 제품은 까다로운 절차 속에서 나오는 Good Manufacturing Product 입니다.)

MFDS(식품의약품안전처)에서 제공하는 바이오시밀러 평가 매뉴얼을 확인해보세요

Click Here >>

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

R&D SYSTEMS
a bio-techne brand

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

1845-GMP-025

Certificate of Analysis

Size: 25µg
Lot: GACZ0219021

Description

Source	*E. coli*-derived human Sonic Hedgehog/Shh protein Cys24-Gly197 (Cys24Ile-Ile), 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 Analysis	Met-Ile-Ile-Gly_{25}-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 ED_{50} for this effect is 0.1-0.4 µg/mL. When this lot of rhSHH was assayed on 02/18/19, the ED_{50} was 0.278 µg/mL. The ED_{50} 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 conditions
Endotoxin Level	<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.
Host Cell Protein	<0.5 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
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 Agar

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Manufacturing Specifications

GMP Proteins
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 Factors and Cytokines Used in Cell Therapy Manufacturing.

Certificate of Analysis

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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 acknowledgment 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 <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