Recombinant Human Noggin GMP

Catalog Number: 6057-GMP

DESCRIPTION

Source	Mouse myeloma cell line, NS0-derived Gln28-Cys232 Accession # Q13253 Manufactured and tested under current Good Manufacturing Practice (GMP) guidelines.
N-terminal Sequence Analysis	Amino acid sequencing was blocked, suggesting it is consistent with Gln28 as the first N-terminal amino acid. Predicted N-terminal sequence: Gln-His-Tyr-Leu-His-Ile-Arg-Pro-Ala-Pro
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	23 kDa (monomer)

SPECIFICATIONS

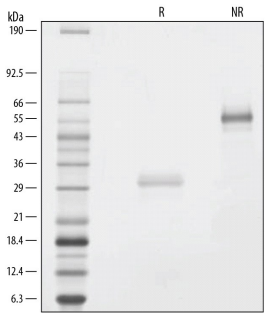
SDS-PAGE	30-33 kDa, reducing conditions
Activity	Measured by its ability to inhibit BMP-4-induced alkaline phosphatase production by ATDC5 mouse chondrogenic cells. The ED_{50} for this effect is typically 0.04–0.2 µg/mL in the presence of 50 ng/mL of Recombinant Human BMP-4 (Catalog # 314-BP).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with silver staining, under reducing conditions.
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100 µg/mL in PBS.
Shipping	The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	**Use a manual defrost freezer and avoid repeated freeze-thaw cycles.** ● 12 months, -20 to -70 °C as supplied. ● 1 month, 2 to 8 °C under sterile conditions after reconstitution. ● 3 months, -20 to -70 °C under sterile conditions after reconstitution.

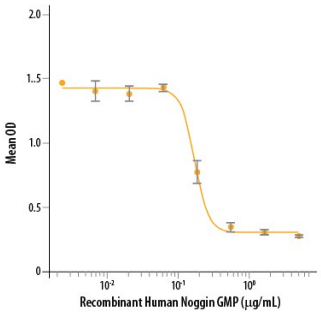
DATA

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human Noggin (Catalog # 6057-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by silver staining, showing bands at 31 kDa and 57 kDa, respectively.

Bioactivity



GMP-grade Recombinant Human Noggin (Catalog # 6057-GMP) inhibits BMP-4-induced alkaline phosphatase production in the ATDC5 mouse chondrogenic cell line. The ED_{50} for this effect is typically 0.04–0.2 µg/mL in the presence of 50 ng/mL of Recombinant Human BMP-4 (Catalog # 314-BP).

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BACKGROUND

R&D Systems' 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.

R&D Systems' quality focus includes:

- Manufacturing and testing under an ISO 9001:2008 and ISO 13485:2003 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, mass spectrometry results, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP sterility testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in *ex vivo* cell therapy applications. They are not for *in vivo* use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

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