Recombinant Human/Mouse/Rat GDF-8/Myostatin GMP

Catalog Number: 788-GMP

DESCRIPTION

Source	Mouse myeloma cell line, NS0-derived Asp268-Ser376 Accession # O08689 Manufactured and tested under current Good Manufacturing Practice (GMP) guidelines.
N-terminal Sequence Analysis	Asp-Phe-Gly-Leu-Asp-(Cys)-Asp-Glu-His-Ser
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	12.4 kDa

SPECIFICATIONS

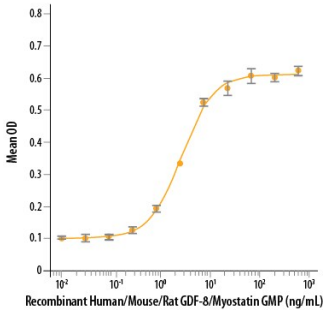
SDS-PAGE	12 kDa, reducing conditions 24 kDa, non-reducing conditions
Activity	Measured by its ability to induce hemoglobin expression in K562 human chronic myelogenous leukemia cells. Schwall, R.H. *et al*. (1991) Method Enzymol. **198**:340. The ED_{50} for this effect is 2-10 ng/mL.
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>90%, by SDS-PAGE with silver staining.
Host Cell Protein	<5.0 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
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 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.** ● A minimum of 6 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date. ● 1 month, 2 to 8 °C under sterile conditions after reconstitution. ● 3 months, ≤ -20 °C under sterile conditions after reconstitution.

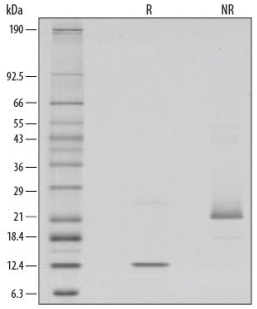
DATA

Bioactivity



GMP-grade Recombinant Human/Mouse/Rat GDF-8/Myostatin (Catalog # 788-GMP) induces hemoglobin expression in the K562 human chronic myelogenous leukemia cell line. The ED_{50} for this effect is 2-10 ng/mL.

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human/Mouse/Rat GDF-8/Myostatin (Catalog # 788-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by silver staining, showing the main bands at 12 kDa and 24 kDa, respectively.

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BACKGROUND

Growth Differentiation Factor 8 (GDF-8), also known as myostatin, is a member of the TGF-β superfamily that is expressed specifically in developing and adult skeletal muscle. GDF-8 cDNA encodes a 376 amino acid (aa) prepropeptide with a 24 aa residue signal peptide, a 223 aa residue amino-terminal propeptide, and a 109 aa residue carboxy-terminal mature protein. Mature GDF-8 contains the canonical 7-cysteine motif common to other TGF-β superfamily members. Similar to the TGF-βs, activins and BMP-11, GDF-8 also contains one extra pair of cysteine residues that is not found in other family members. The bioactive form of GDF-8 is a homodimer with an apparent molecular weight of approximately 25 kDa. GDF-8 is highly conserved across species. At the amino acid sequence level, mature human, mouse, rat and cow GDF-8 are 100% identical. Within the TGF-β superfamily, GDF-8 is most closely related to BMP-11, a mammalian protein that acts as a dorsal mesoderm and neural inducer in *Xenopus* explants. The two proteins share 90% amino acid sequence identity within their mature chain. A targeted disruption of GDF-8 in mouse results in large mice with a widespread increase in skeletal muscle mass, indicating that GDF-8 is a negative regulator of skeletal muscle growth. A mutation in the bovine GDF-8 gene has been shown to be responsible for the double-muscled phenotype in cattle breeds such as Belgian Blue cattle that is characterized by an increase in muscle mass. GDF-8 has also been shown to inhibit preadipocyte differentiation to adipocytes. Mature GDF-8 binds to activin type II receptors and the binding is antagonized by the activin-binding protein, follistatin. R&D Systems recombinant GDF-8 preparations have been shown to act similarly to Activin A in both the *Xenopus* animal cap and the K562 assays.

References:

1. Storm, E.E. *et al.* (1994) Nature **368**:639.
2. Sharma, M. *et al.* (1999) J. Cell Physiol. **180**:1.
3. McPherron, A.C. *et al.* (1997) Nature **387**:83.
4. Lee, S.J. *et al.* (2001) Proc. Natl. Acad. Sci. USA **98**:9306.
5. Kim, H.S. *et al.* (2001) Biochem. Biophys. Res. Commun. **281**:902.

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.

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- Personnel training programs
- Raw material testing and vendor qualification/monitoring
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- Equipment calibration schedules using a computerized calibration program
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- Material review process for variances
- Monitoring of stability over product shelf-life

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- N-terminal amino acid analysis, SDS-PAGE analysis, 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)
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

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