

DESCRIPTION

Source	Mouse myeloma cell line, NS0-derived GDF-8/Myostatin protein Asp268-Ser376 Accession # O08689.1 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

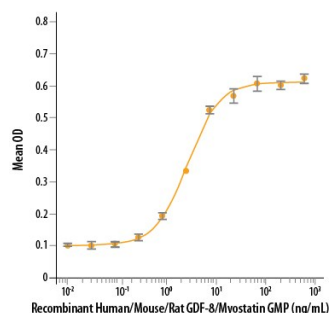
SDS-PAGE	12 kDa, reducing conditions 24 kDa, non-reducing conditions
Activity	Measured by its ability to induce hemoglobin expression in K562 human chronic myelogenous leukemia cells. Schwall, R.H. <i>et al.</i> (1991) Method Enzymol. 198 :340. The ED ₅₀ for this effect is 2-10 ng/mL.
Endotoxin Level	<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 for Mycoplasma.
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. <ul style="list-style-type: none"> A minimum of 12 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.

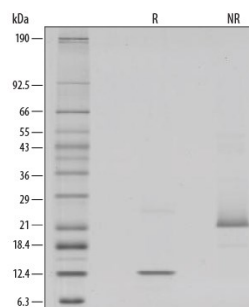
DATA

Bioactivity



Recombinant Human/Mouse/Rat GDF-8/Myostatin GMP Protein 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 ED₅₀ for this effect is 2-10 ng/mL.

SDS-PAGE



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

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- β s, 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-muscling 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: USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and Eu. Ph. 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 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, 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 testing according to USP
- 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.

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 GMP grade products for preclinical or clinical *ex vivo* use. They are not for *in vivo* use. Please read the following End User Terms prior to using this product.

PRODUCT SPECIFIC NOTICES**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.

We suggest you print and retain a copy of these End User Terms of Use of Product for your records.

The End User is aware that R&D Systems, Inc. sells GMP products for preclinical or clinical *ex vivo* use and not for *in vivo* use. The End User further agrees, as a condition of the sale of R&D Systems' GMP products that: a) the End User will not use this GMP Product in any procedure wherein the product may be directly or indirectly administered to humans, unless the End User has obtained, or prior to their use will have obtained, an Investigational New Drug (IND) exemption from the FDA and will use the product only in accordance with the protocols of such IND and of the Institutional Review Board overseeing the proposed research, or b) the End User will use the products outside of the United States in accordance with the protocols of research approved by the Institutional Review Board or authorized ethics committee and regulatory agencies to which the End User is subject to in their territory.

R&D Systems, Inc. has the right, at its sole discretion, to modify, add or remove any terms or conditions of these End User Terms of Use without notice or liability to you. Any changes to these End User Terms of Use are effective immediately following the printing of such changes on this product insert. The most recent version of these End User Terms of Use of Product may be found at: [RnDSystems.com/Legal](https://www.rndsystems.com/legal).

You agree to review these End User Terms of Use of Product to ensure any subsequent use by you of R&D Systems' GMP Products following changes to these End User Terms of Use of Product constitutes your acceptance of all such changes.

TERMS AND CONDITIONS

The following limitation applies to R&D Systems' warranty and liability for damages: All products are warranted to meet R&D Systems' published specifications when used under normal laboratory conditions.

R&D SYSTEMS DOES NOT MAKE ANY OTHER WARRANTY OR REPRESENTATION WHATSOEVER, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO ITS PRODUCTS. IN PARTICULAR, R&D SYSTEMS DOES NOT MAKE ANY WARRANTY OF SUITABILITY, NONINFRINGEMENT, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

NOTWITHSTANDING ANY OTHER PROVISIONS OF THESE TERMS AND/OR ANY OTHER AGREEMENT BETWEEN R&D SYSTEMS AND PURCHASER FOR THE PURCHASE OF THE PRODUCTS, R&D SYSTEMS' TOTAL LIABILITY TO PURCHASER ARISING FROM OR IN RELATION TO THESE TERMS, AN AGREEMENT BETWEEN THE PARTIES OR THE PRODUCTS, WHETHER ARISING IN CONTRACT, TORT OR OTHERWISE SHALL BE LIMITED TO THE TOTAL AMOUNT PAID BY PURCHASER TO R&D SYSTEMS FOR THE APPLICABLE PRODUCTS. IN NO EVENT WILL R&D SYSTEMS BE LIABLE FOR THE COST OF PROCUREMENT OF SUBSTITUTE GOODS.

Full details of R&D Systems' Terms and Conditions of Sale can be found online at: [RnDSystems.com/Legal](https://www.rndsystems.com/legal).