

**DESCRIPTION**

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

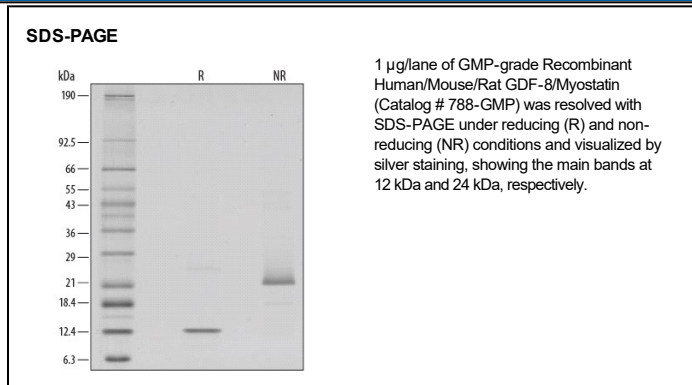
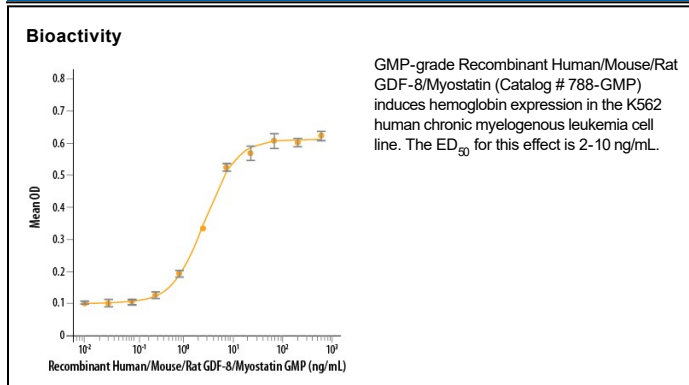
**SPECIFICATIONS**

|                          |   |
|--------------------------|---|
| <b>SDS-PAGE</b>          | 12 kDa, reducing conditions<br>24 kDa, non-reducing conditions  |
| <b>Activity</b>          | Measured by its ability to induce hemoglobin expression in K562 human chronic myelogenous leukemia cells. Schwall, R.H. <i>et al.</i> (1991) <i>Method Enzymol.</i> <b>198</b> :340.<br>The ED <sub>50</sub> for this effect is 2-10 ng/mL. |
| <b>Endotoxin Level</b>   | <0.10 EU per 1 µg of the protein by the LAL method.   |
| <b>Purity</b>            | >90%, by SDS-PAGE with silver staining.   |
| <b>Host Cell Protein</b> | <5.0 ng per µg of protein when tested by ELISA.   |
| <b>Mycoplasma</b>        | Negative when tested in a ribosomal RNA hybridization assay.  |
| <b>Formulation</b>       | Lyophilized from a 0.2 µm filtered solution in Acetonitrile and TFA. See Certificate of Analysis for details.   |

**PREPARATION AND STORAGE**

|                                |   |
|--------------------------------|---|
| <b>Reconstitution</b>          | Reconstitute at 100 µg/mL in 4 mM HCl.  |
| <b>Shipping</b>                | The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.   |
| <b>Stability &amp; Storage</b> | <b>Use a manual defrost freezer and avoid repeated freeze-thaw cycles.</b> <ul style="list-style-type: none"> <li>• A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.</li> <li>• 1 month, 2 to 8 °C under sterile conditions after reconstitution.</li> <li>• 3 months, ≤ -20 °C under sterile conditions after reconstitution.</li> </ul> |

**DATA**



## BACKGROUND

Growth Differentiation Factor 8 (GDF-8), also known as myostatin, is a member of the TGF- $\beta$  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- $\beta$  superfamily members. Similar to the TGF- $\beta$ 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- $\beta$  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: 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:

- 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 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.

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

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