RD SYSTEMS a biotechne brand

Recombinant Human BMP-7 GMP

Catalog Number: 354-GMP

DESCRIPTION	
Source	Chinese Hamster Ovary cell line, CHO-derived human BMP-7 protein
	Ser293-His431
	Accession # P18075
	Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ser-Thr-Gly-Ser-Lys-Gln-Arg-Ser-Gln-Asn
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	15.7 kDa (monomer)

SPECIFICATIONS	
SDS-PAGE	18-24 kDa, reducing conditions
Activity	Measured by its ability to induce alkaline phosphatase production by ATDC5 mouse chondrogenic cells. Nakamura, K. <i>et al.</i> (1999) Exp. Cell Res. 250 :351. The ED ₅₀ for this effect is 0.1-0.6 μg/mL.
Endotoxin Level	<0.01 EU per 1 µg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with silver staining, under reducing conditions.
Host Cell Protein	< 0.5 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 100-200 µg/mL in sterile 4 mM HCI.
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.



GMP-grade Recombinant Human BMP-7 (Catalog # 354-GMP) induces alkaline phosphatase production in the ATDC5 mouse chondrogenic cell line. The ED₅₀ for this effect is 0.1-0.6 µg/mL. Three independent lots were tested for activity and plotted on the same graph to show lot-to-lot consistency of GMP BMP-7.



12.4

6.3 -

1 µg/lane of Recombinant Human GMPgrade BMP-7 (Catalog # 354-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by silver staining, showing multiple R bands at 19 and 23 kDa and multiple NR bands at 31, 37 and 58 kDa. Multiple bands under reducing conditions are due to variable glycosylation.

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BACKGROUND

Bone morphogenetic protein 7 (BMP-7), also known as osteogenic protein 1 (OP-1), is a widely expressed TGF-β superfamily member with important functions during embryogenesis, in the adult, and in disease (1, 2). Human BMP-7 is synthesized with a 29 amino acid (aa) signal sequence, a 263 aa propeptide, and a 139 aa growth factor domain (3, 4). The growth factor domain of human BMP-7 shares 98% aa sequence identity with mouse and rat BMP-7. The BMP-7 propeptide is cleaved intracellularly but remains in association with the growth factor domain. BMP-7 is subsequently secreted as a tetramer that consists of two propeptides and two disulfide-linked growth factor domains (5, 6). Mature BMP-7 can also form disulfide-linked heterodimers with BMP-2 or BMP-4, complexes that show increased potency and range of activity compared to BMP-7 homodimers (7-9). The presence of the propeptides in the BMP-7 tetramer does not diminish the bioactivity of the growth factor domains (6). Secreted BMP-7 is immobilized in the extracellular matrix as a result of interactions between the propeptide and matrix Fibrillin (5). BMP-7 exerts its biological effects through the type 2 receptors Activin RIIA, Activin RIIB, and BMPR-II and the type 1 receptors Activin RIA, BMPR-IA, and BMPR-IB (2, 6). BMP-7 plays a role in a variety of organ systems. It promotes new bone formation and nephron development (10, 11), inhibits the branching of prostate epithelium (12), and antagonizes epithelial-mesenchymal transition (EMT) (13-15). In pathological conditions, BMP-7 inhibits tumor growth and metastasis (14), ameliorates fibrotic damage in nephritis (13), and promotes neuroregeneration following brain ischemia (16).

References:

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- 6. Sengle, G. *et al.* (2008) J. Mol. Biol. **381**:1025.
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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.

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.

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.

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