# Recombinant Human Hepsin GMP

Catalog Number: 4776-GMP

## DESCRIPTION

| | |
|---|---|
| **Source** | Mouse myeloma cell line, NS0-derived<br>Arg45-Leu417 (Asp161Glu & Arg162Lys), with a C-terminal 10-His tag<br>Accession # P05981<br>Manufactured and tested under cGMP guidelines. |
| **N-terminal Sequence Analysis** | $Arg_{45}$-Ser-Asp-Gln-Glu-Pro-Leu-Tyr-Pro-Val |
| **Predicted Molecular Mass** | 42 kDa |

## SPECIFICATIONS

| | |
|---|---|
| **SDS-PAGE** | 40-43 kDa, reducing conditions |
| **Activity** | Measured by its ability to cleave *tert*-butoxycarbonyl-Gln-Arg-Arg-7-amino-4-methylcoumarin (Boc-QRR-AMC).<br>The specific activity is >20,000 pmol/min/µg, as measured under the described conditions. See Activity Assay Protocol on www.RnDSystems.com. |
| **Endotoxin Level** | <1.0 EU per 1 µg of the protein by the LAL method. |
| **Purity** | >95%, by SDS-PAGE with silver staining, under reducing conditions. |
| **Formulation** | Supplied as a 0.2 µm filtered solution in Sodium Acetate and NaCl. See Certificate of Analysis for details. |

## Activity Assay Protocol

**Materials**

- Activation Buffer: 0.1 M Tris, 10 mM $CaCl_2$, 0.15 M NaCl, 0.05 % Brij-35, pH 8.0
- Assay Buffer: 50 mM Tris, pH 9.0
- Recombinant Human Hepsin (rhHepsin) (Catalog # 4776-SE)
- Fluorogenic Peptide Substrate: BOC-Gln-Arg-Arg-AMC (Bachem, Catalog # I-1655), 5 mM stock in 50:50 DMSO:Methanol
- F16 Black Maxisorp Plate (Nunc, Catalog # 475515)
- Fluorescent Plate Reader (Model: SpectraMax Gemini EM by Molecular Devices) or equivalent

**Assay**

1. Dilute rhHepsin to 100 µg/mL in Activation Buffer.
2. Incubate at 37 °C for 24 hours.
3. Dilute activated rhHepsin to 0.2 ng/µL in Assay Buffer.
4. Dilute Substrate to 200 µM in Assay Buffer.
5. Load 50 µL of the 0.2 ng/µL rhHepsin in a black well plate and start the reaction by adding 50 µL of 200 µM Substrate. Include a Substrate Blank containing 50 µL Assay Buffer and 50 µL of 200 µM Substrate.
6. Read at excitation and emission wavelengths of 380 nm and 460 nm (top read), respectively in kinetic mode for 5 minutes.
7. Calculate specific activity:

$$\text{Specific Activity (pmol/min/µg)} = \frac{\text{Adjusted } V_{max}\text{* (RFU/min) x Conversion Factor** (pmol/RFU)}}{\text{amount of enzyme (µg)}}$$

*Adjusted for Substrate Blank

**Derived using calibration standard 7-Amino, 4-Methyl Coumarin (AMC) (Sigma, Catalog # A-9891).

**Final Assay Conditions**

Per Well:

- rhHepsin: 0.010 µg
- Substrate: 100 µM

## PREPARATION AND STORAGE

**Shipping**

The product is shipped with dry ice or equivalent. 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, -70 °C as supplied.
- 3 months, -70 °C under sterile conditions after opening.



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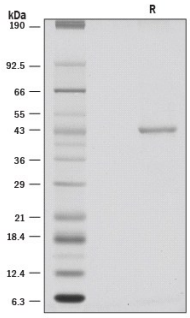
## DATA

### SDS-PAGE




1 µg/lane of Recombinant Human GMP-grade Hepsin (Catalog # 4776-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a band at 43 kDa.

## 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, 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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