



GMP-grade IL-2, IL-7, and IL-15 Cell Therapy Manufacturing

Scalable, seamless translation

scaleready.com



R&D Systems™ GMP-grade Recombinant Human IL-2, GMP-grade Recombinant Human IL-7 and GMP-grade Recombinant Human IL-15 are now being produced in our new state-of-the-art, animal-free GMP manufacturing facility located in St. Paul, MN, USA.



Key Benefits Our New GMP-Grade IL-2, IL-7 and IL-15 Proteins Offer to Customers

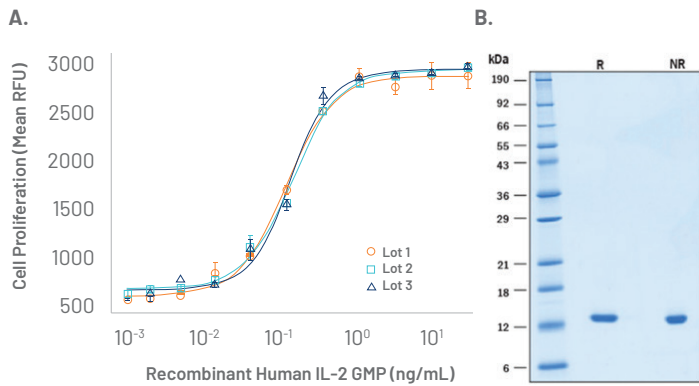
- **New GMP-grade IL-2 Contains the Same Cysteine to Serine Mutation found in Proleukin®:** This mutation has been reported to prevent cysteine mispairing in E.coli that can lead to protein aggregation and makes our new GMP-grade IL-2 protein soluble in injectable-grade water.
- **Lot-to-Lot Consistency:** All new lots of GMP-grade IL-2, IL-7 and IL-15 are rigorously tested to ensure consistency with previous lots and with a master lot, so you don't have to worry whether results will be reproducible over time.
- **Meeting Demand from Process Development to Commercialization:** The proteins are produced in a facility that is optimized for scale to meet the growing demand.
- **Reservable Lots:** Entire lots can be reserved to accommodate long-term needs, preventing you from having to spend time and money on requalification.
- **Manufactured by a Trusted Partner:** The proteins are developed, manufactured, and tested by R&D Systems manufacturing, quality, and regulatory teams, which have over 40 years of protein manufacturing experience. We provide full product transparency, resources to answer any questions you may have, custom bottling options, and facility visits and audits.



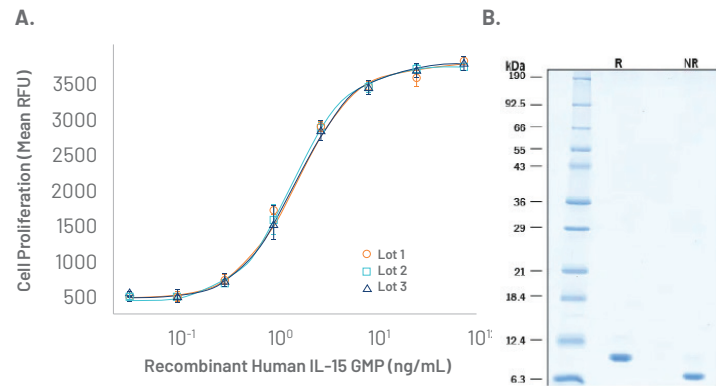
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Application Data

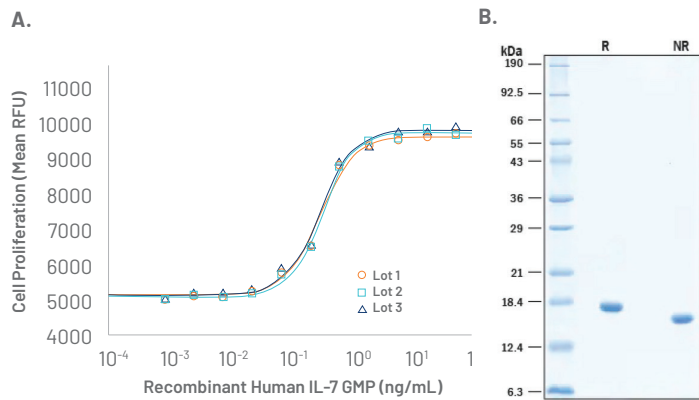
R&D Systems' New GMP-grade Recombinant Human IL-2, IL-7, and IL-15 Proteins Display High Lot-to-Lot Consistency and Purity



Analysis of Activity, Lot-to-Lot Consistency, and Purity of GMP-grade Recombinant Human IL-2. (A) Three independent lots of GMP-grade Recombinant Human IL-2 (R&D Systems, Catalog # BT-002-GMP) were tested for their ability to stimulate proliferation of the CTLL-2 mouse cytotoxic T cell line. Each trace on the graph represents data obtained from GMP-grade Recombinant Human IL-2 from a different manufacturing run, demonstrating the lot-to-lot consistency of the protein. (B) SDS-PAGE analysis of GMP-grade Recombinant Human IL-2 (R&D Systems, Catalog # BT-002-GMP) under reducing (R) and non-reducing (NR) conditions and visualization by Coomassie® Blue staining.



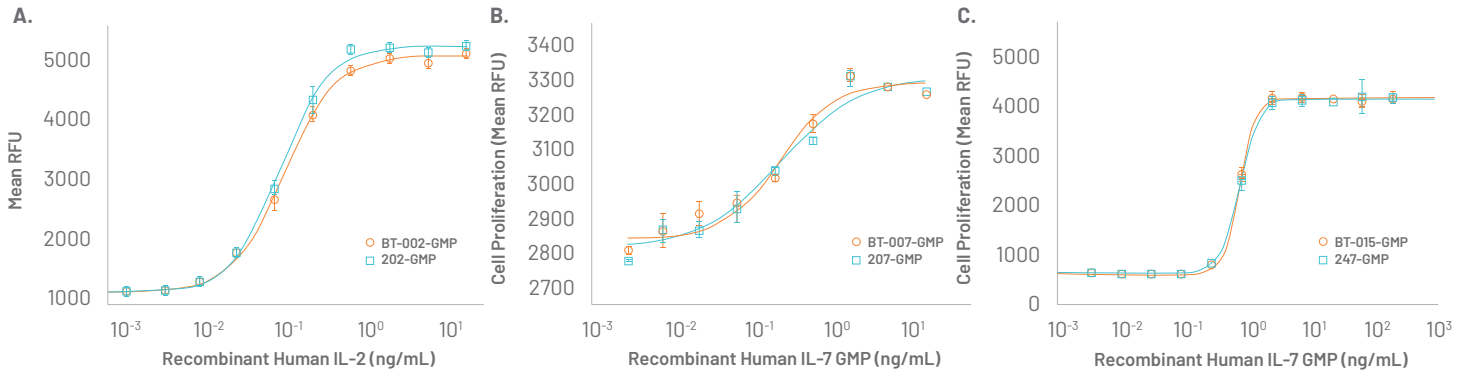
Analysis of Activity, Lot-to-Lot Consistency, and Purity of GMP-grade Recombinant Human IL-15. (A) Three independent lots of GMP-grade Recombinant Human IL-15 (R&D Systems, Catalog # BT-015-GMP) were tested for their ability to stimulate proliferation in the M07e human megakaryocytic leukemic cell line. Each trace on the graph represents data obtained from GMP-grade Recombinant Human IL-15 from a different manufacturing run, demonstrating the lot-to-lot consistency of the protein. (B) SDS-PAGE analysis of GMP-grade Recombinant Human IL-15 (R&D Systems, Catalog # BT-015-GMP) under reducing (R) and non-reducing (NR) conditions and visualization by Coomassie® Blue staining.



Analysis of the Activity, Lot-to-Lot Consistency, and Purity of GMP-grade Recombinant Human IL-7. (A) Three independent lots of GMP-grade Recombinant Human IL-7 (R&D Systems, Catalog # BT-007-GMP) were tested for their ability to stimulate proliferation of PHA-activated human peripheral blood lymphocytes. Each trace on the graph represents data obtained from GMP-grade Recombinant Human IL-7 from a different manufacturing run, demonstrating the lot-to-lot consistency of the protein. (B) SDS-PAGE analysis of GMP-grade Recombinant Human IL-7 (R&D Systems, Catalog # BT-007-GMP) under reducing (R) and non-reducing (NR) conditions and visualization by Coomassie® Blue staining.

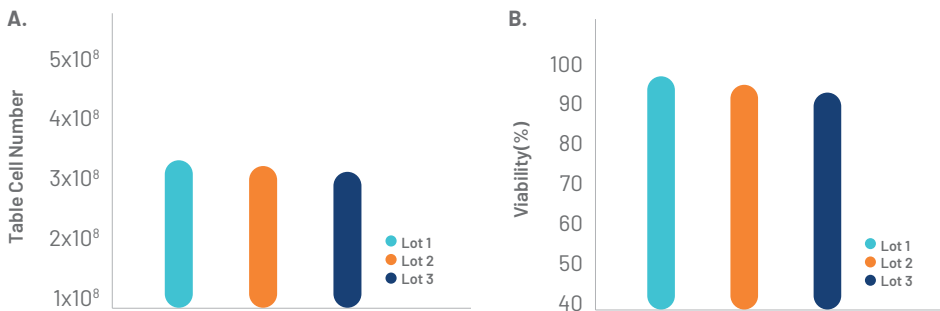


Comparison of Our New GMP-grade Recombinant Human IL-2, IL-7, and IL-15 Proteins with the Original GMP-grade IL-2, IL-7, and IL-15 Proteins



GMP-grade Recombinant Human IL-2, IL-7, and IL-15 Proteins Produced in the New GMP Facility Display Similar Bioactivity as the Original GMP-grade Recombinant Human IL-2, IL-7, and IL-15 Proteins. (A) The bioactivity of GMP-grade Recombinant Human IL-2 (R&D Systems, Catalog # BT-002-GMP) manufactured in the new GMP facility was compared to the bioactivity of the original GMP-grade Recombinant Human IL-2 (R&D Systems, Catalog # 202-GMP) by testing the ability of the proteins to stimulate proliferation of the CTLL-2 mouse cytotoxic T cell line. (B) The bioactivity of GMP-grade Recombinant Human IL-7 (R&D Systems, Catalog # BT-007-GMP) manufactured in the new GMP facility was compared to the bioactivity of the original GMP-grade Recombinant Human IL-7 (R&D Systems, Catalog # 207-GMP) by testing the ability of the proteins to stimulate proliferation of the PHA-activated human peripheral blood lymphocytes. The bioassay data for the new GMP-grade IL-7 protein is nearly identical to the original GMP-grade IL-7 with ED50 values within the margin of error. (C) The bioactivity of GMP-grade Recombinant Human IL-15 (R&D Systems, Catalog # BT-015-GMP) manufactured in the new GMP facility was compared to the bioactivity of the original GMP-grade Recombinant Human IL-15 (R&D Systems, Catalog # 247-GMP) by testing the ability of the proteins to stimulate proliferation in the M07e human megakaryocytic leukemia cell line. The bioassay data for the new GMP-grade IL-15 protein is nearly identical to the original GMP-grade IL-15 with ED50 values within the margin of error.

Cell Yield and Viability of T Cells After G-Rex® Culture in Media Containing the New GMP-grade IL-7 and IL-15 Proteins



Analysis of the Total Cell Number and Viability of T Cells After G-Rex® Culture in Media Containing GMP-grade Recombinant Human IL-7 and IL-15. CD4⁺ and CD8⁺ T cells isolated from a human donor were cultured in a G-Rex® 6M Well Plate containing media with one of three lots of GMP-grade Recombinant Human IL-7 and IL-15 (R&D Systems, Catalog # BT-007-GMP and Catalog # BT-015-GMP). The average (A) cell yield and (B) cell viability for each lot of cytokines were determined by flow cytometry on day 14. G-Rex® is a registered trademark of Wilson Wolf Corporation.

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