GCSF PK ELISA Catalog EL-1611-73196

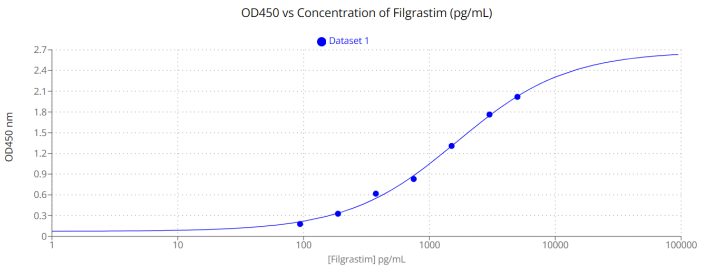
For the determination of GCSF in serum and plasma.

Introduction

Filgrastim (Granulocyte colony-stimulating factor (G-CSF or GSCF)), also known as colony-stimulating factor 3 (CSF 3), is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream. The pharmaceutical analogs of naturally occurring G-CSF are called filgrastim and lenograstim. Filgrastim is used to treat neutropenia,[9] stimulating the bone marrow to increase production of neutrophils. Causes of neutropenia include chemotherapy and bone marrow transplantation. This assay employs the indirect sandwich enzyme immunoassay technique to quantitate filgrastim in human serum and/or plasma.

Calibration Curve

A stock solution of Filgrastim (USP) in immunoassay buffer at 5 µg/mL was used to prepare a calibration curve in human serum. These calibrators were then further diluted 1/100 in immunoassay buffer to give a standard range of 5000 pg/mL to 93.75 pg/mL. Calibration curves were calculated using a four-parameter fit, and unknowns were back calculated using the curve.



Lower Limit of Quantitation (LLOQ)

Blank samples of unique sera were below the LLOQ and met the acceptance criteria of ≥ 80% of blank samples being below the LLOQ. Blank hemolyzed samples and the blank lipaemic samples were below the LLOQ and met the acceptance criteria of ≥ 80% of blank samples being below the LLOQ

Specificity

In presence of interfering materials, M-CSF, GM-CSF, and IL-3, all levels of filgrastim met the acceptance criteria of having a % error of ± 20% for concentrations of 3000 ng/mL, 1500 ng/mL, 750 ng/mL, 375 ng/mL and 187.5 ng/mL and a % error of ± 25% for concentrations of 5000 ng/mL (ULOQ) and 93.75 ng/mL (LLOQ).

Accuracy and Precision

All replicates for Accuracy and Precision runs 1 -6 met the acceptance criteria of % error of ± 25% for ULOQ (5000 pg/mL) and LLOQ (93.75 pg/mL) and ± 20% for HQC, MQC and LQC (3000, 750, and 187.5 pg/mL The %CV of ± 25% for ULOQ (5000 pg/mL) and LLOQ (93.75 pg/mL) and ± 20% for HQC, MQC and LQC (3000, 750, and 187.5 pg/mL) between runs met this acceptance criteria.

Sensitivity

The acceptance criteria for accuracy of ± 25% of nominal concentration for six runs of LLOQ (three replicates for each run) was met for each run.

Freeze/Thaw of Standards

All replicates for Freeze/Thaw Stability met the acceptance criteria of % error of ± 25% for ULOQ (5000 pg/mL) and LLOQ (93.75 pg/mL) and ± 20% for HQC, MQC and LQC (3000, 750, and 187.5 pg/mL).

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