



## Validation and Application of a Sensitive ELISA to Quantify rec-GCSF for Preventing Cross-Contamination in Recombinant Proteins Produced in a Multi-Product Facility

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**SUMMARY.** Production of pharmaceuticals in a multi-product facility involves challenges such as the demonstration of the residue elimination to prevent cross-contamination among products. It is a difficult task because of sensitive quantification assay non-availability and for protein primary structure modification provoked by some sanitizing agents. In this sense, a sensitive ELISA for detecting recombinant granulocyte colony stimulating factor (rec-GCSF) was validated and applied for quantifying it even in others recombinant protein samples in this study. In conclusion, the immunoassay was useful for the rec-GCSF detection up to nanogram level without cleaning in place procedure solution interferences. Rec-GCSF potential contamination level of purification steps employed in recombinant protein production processes done in the same facility was several times lower than toxic rec-GCSF doses. Therefore, it demonstrated rec-GCSF amount that could be potentially present in final doses of recombinant proteins subsequently produced in the same facility was categorically undetected and without any impact on subsequently produced protein quality.

**KEY WORDS:** Enzyme-linked immunosorbent assay, Granulocyte colony stimulating factor, Multi-product facility.

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