

**Specification Sheet**  
**Filgrastim Concentrated Solution, EP**

**Description:**

Filgrastim concentrated solution is a solution of a protein having primary structure of the granulocyte colony-stimulating factor plus 1 additional amino acid, an N-terminal methionine (r-met HU G-CSF). In contrast to its natural counterpart, the protein is not glycosylated. Human G-CSF is produced and secreted by endothelium, monocytes and other immune cells. The protein stimulates the differentiation and proliferation of leucocytes stem cells into mature granulocytes.

**Production:**

Filgrastim concentrated solution is produced by a method based on recombinant DNA (rDNA) technology, using bacteria as host cells. Prior to release the following tests are carried out on each batch of the final bulk product, unless exemption has been granted by the competent authority.

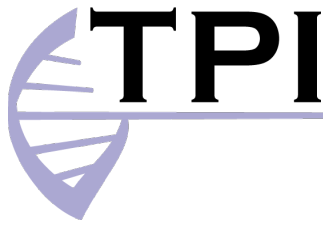
**Storage:**

The material is shipped frozen on dry-ice. Upon receipt, store the material at 2-6°C.

**Shelf Life:**

The material has a shelf life of not less than 24 months when stored at 2-6°C.

Test	Attribute	Specification
Appearance	Quality	Clear, colorless or slightly yellowish liquid
pH	Quality	4.0 ± 0.3
SDS-PAGE (Reduced)	Identity	The principal band for the 100 µg/mL sample has migrated to a similar position as the principal band in the 100 µg/mL standard
	Purity	No impurity band is more intense than the 2 µg/mL reference standard principal band
SDS-PAGE (Non-reduced)	Identity	The principal band for the 100 µg/mL sample has migrated to a similar position as the principal band in the 100 µg/mL standard
	Purity	No impurity band is more intense than the 2 µg/mL reference standard principal band



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IEF	Identity	The principal band for the test solution is similar in position to the principal band for the reference standard loaded at 6.0µg/well position representing the 0.3 mg/mL reference solution as listed in the EP
	Purity	For impurities, no band in the sample (other than the principal band) is more intense than the principal band for the reference standard loaded at 0.6 µg/well representing 0.03 mg/mL reference standard in the EP
Bacterial Endotoxins	Safety	< 2 IU in the volume that contains 1.0 mg of protein
SEC-HPLC	Identity	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution
	Purity	Total percentage of all peaks with retention times less than the principal peak ≤ 2 %
RP-HPLC	Potency	Assay: Filgrastim content ≥ 0.9 mg/mL
	Purity	Related Proteins: Any impurity ≤ 2.0% Total impurity ≤ 3.5%
Peptide Mapping	Identity	The profile of the chromatogram obtained with the test solution corresponds to that of the chromatogram obtained with the reference solution
Host Cell Proteins	Safety	≤ 100 ppm (100ng/mg)
Residual DNA	Safety	To meet regulatory requirements
Cell Assay	Potency	Estimated potency between 80 and 125 % of stated potency of 1.0 x 10 <sup>8</sup> IU/mg Confidence limits (P=0.95) between 74 and 136 % of the estimated potency
Bioburden	Safety	≤ 10 CFU/mL