Recombinant Human Pegylated Granulocyte-Colony Stimulating Factor (rh PEG-G-CSF)

Synonyms: none

Description: Recombinant human PEG-G-CSF produced in *E.Coli* is a non-glycosylated polypeptide chain containing 175 amino acids and having a molecular mass of 18800 Dalton. The rh PEG-G-CSF is manufactured by attaching a 20000 Dalton methoxypolyethylene glycol propionaldehyde (mPEG-ALD) to the N-terminal amino acid of G-CSF having a total molecular mass of 38800 Dalton. rh PEG-G-CSF is purified by proprietary chromatographic techniques.

Source: *Escherichia Coli*.

Physical Appearance: Sterile filtered clear solution.

Formulation: The protein was extensively dialyzed against 10 mM sodium acetate buffer pH = 4 and 5 % mannitol was added.

Stability: rh PEG-G-CSF although stable at 15°C for 1 week, should be stored between 2-8°C. For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA).

Purity:
Greater than 95.0% as determined by:
(a) Analysis by RP-HPLC.
(b) Anion-exchange FPLC.
(c) Analysis by reducing and non-reducing SDS-PAGE silver stained gel.

Amino acid sequence: The sequence of the first five N-terminal amino acids was determined and was found to be Met-Thr-Pro-Leu-Gly.

Dimers and aggregates: Less than 1% as determined by silver-stained SDS-PAGE gel analysis.

Biological Activity: rh PEG-G-CSF is fully biologically active when compared to standard. The ED$_{50}$, calculated by the dose-dependant proliferation of murine NFS-60 indicator cells (measured by $^3$H-thymidine uptake) is < 0.1 ng/ml, corresponding to a specific activity of 1 x 10$^8$ IU/mg.

Endotoxicity: Less than 0.1 ng/µg (IEU/µg) of rh PEG-G-CSF.

Protein content:
Protein quantitation was carried out by two independent methods:
1. UV spectroscopy at 280 nm using the absorbency value of 0.815 as the extinction coefficient for a 0.1% (1mg/ml) solution. This value is calculated by the PC GENE computer analysis program of protein sequences (IntelliGenetics).

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<th>2 µg</th>
<th>10 µg</th>
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<td>small</td>
<td>Cat.N°</td>
<td>11343232</td>
</tr>
<tr>
<td>medium</td>
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