

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd., manufacturer and supplier of quality chemicals.

Product Name	Filgrastim, European Pharmacopoeia (Ep)
C.A.S. Number	121181-53-1
Molecular Formula	—
Molecular Weight	—
Grade / Standard	Fine chemical grade — assay on specification
Physical Form	Appearance as per specification
Product Category	Fine & Research Chemicals
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	Appearance as per specification	Complies	Visual
2	Identification	Conforms to the structure of the substance	Complies	FTIR / Chemical test
3	Solubility	As per specification	Complies	Visual / Monograph
4	Loss on Drying	Not more than 1.0 % w/w	0.57	Gravimetry
5	Residue on Ignition	Not more than 0.5 % w/w	0.069	Gravimetry
6	Heavy Metals (as Pb)	Not more than 20 ppm	Less than 10 ppm	ICP-OES
7	Structure	Conforms to reference structure	Complies	FTIR / NMR

Remarks

Material supplied against this specification is analysed on every production lot and **conforms** to the limits stated above in all tested parameters. Results shown are the typical values obtained for this grade.

Retained samples are held against every export consignment. Store in tightly closed original packing, in a cool, dry, well-ventilated place away from incompatible materials and direct sunlight.

Checked and Approved by

Prem Panchal
Quality Assurance
Scapex Exports Pvt. Ltd.

This document sets out the standard specification for the product named above and applies to all consignments of this grade. It is issued by Scapex Exports Pvt. Ltd. as manufacturer and supplier. Refer to the Material Safety Data Sheet (MSDS) before handling.