

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	Insulin Human, European Pharmacopoeia (E)
C.A.S. Number	11061-68-0
Molecular Formula	—
Molecular Weight	—
Grade / Standard	≥98% rDNA Origin, Pharma Grade
Physical Form	White lyophilized powder
Product Category	Active Pharmaceutical Ingredients (APIs)
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	White lyophilized powder	Complies	Visual
2	Identification	Conforms to the structure of the substance	Complies	FTIR / Chemical test
3	Solubility	As per specification	Complies	Visual / Monograph
4	Assay	Not less than 98.0 % w/w	98.48	Titrimetry / Instrumental
5	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)
6	pH (1 % w/v aqueous solution)	As per monograph	5.5	Potentiometry
7	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.18	Karl Fischer titration
8	Melting Range / Point	As per monograph	Complies	Capillary method
9	Particle Size (d90)	As per specification	88 µm	Laser diffraction
10	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.