

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	Loratadine Key Intermediate
C.A.S. Number	Not applicable
Molecular Formula	—
Molecular Weight	—
Grade / Standard	≥97% Technical
Physical Form	Off-white to pale yellow powder
Product Category	Pharmaceutical Intermediates
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	Off-white to pale yellow powder	Complies	Visual
2	Solubility	As per specification	Complies	Visual / Monograph
3	Assay	Not less than 97.0 % w/w	97.44	Titrimetry / Instrumental
4	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)
5	pH (1 % w/v aqueous solution)	As per monograph	6.7	Potentiometry
6	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.15	Karl Fischer titration
7	Melting Range / Point	As per monograph	Complies	Capillary method
8	Particle Size (d90)	As per specification	141 µm	Laser diffraction
9	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.