

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd.

Product Name	Levamisole Hydrochloride	C.A.S. Number	16595-80-5
Product Category	Active Pharmaceutical Ingredients (APIs)	Product Group	Antimalarials & Anthelmintics
Grade / Standard	USP/EP	Physical Form	White crystalline powder
Country of Origin	India	Document No.	SCX/COA/6E4295
Packing	Standard export packing — bags, drums, carboys, IBC or ISO tank as applicable	Storage	Cool, dry, well-ventilated place in tightly closed original packing

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	White crystalline powder	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Solubility	As per specification	Complies	Visual / Monograph
5	Assay (on dried basis)	98.0 – 102.0 % w/w	99.87	HPLC / Titrimetry (Monograph)
6	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)
7	pH (1 % w/v aqueous solution)	As per monograph	6.6	Potentiometry
8	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.14	Karl Fischer titration
9	Melting Range / Point	As per monograph	Complies	Capillary method
10	Particle Size (d90)	As per specification	124 µm	Laser diffraction
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.030	Gravimetry (Monograph)
12	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
13	Related Substances — any individual impurity	Not more than 0.10 %	0.014	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.096	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC

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 not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with each consignment. The information is given in good faith; it does not constitute a warranty of fitness for any particular purpose. Refer to the Safety Data Sheet before handling.