

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	Ketotifen Fumarate
C.A.S. Number	34580-13-7
Molecular Formula	—
Molecular Weight	—
Grade / Standard	EP
Physical Form	White to off-white crystalline powder
Product Category	Active Pharmaceutical Ingredients (APIs)
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	White to off-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	99.28	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	5.8	Potentiometry
8	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.09	Karl Fischer titration
9	Melting Range / Point	As per monograph	Complies	Capillary method
10	Particle Size (d90)	As per specification	106 µm	Laser diffraction
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.054	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 %	0.037	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.196	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
16	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.