

Certificate of Analysis Summary

Ketotifen Fumarate EP11

Parameter	Value
Product	Ketotifen Fumarate EP11
Batch Number	20260120
Manufacturing Date	20-Jan-2026
Expiry Date	19-Jan-2029
CAS Number	34580-14-8
Molecular Weight	425.50

Test	Specification	Result
Appearance	White to brownish-yellow fine crystalline powder	Conforms
Solubility	Sparingly soluble in water; slightly soluble in methanol	Conforms
Identification	TLC, IR	Positive
Appearance of Solution	Clear & ≤ BY4	< BY4
Sulfated Ash	≤ 0.1%	0.05%
Loss on Drying	≤ 0.5%	0.11%
Impurity A	≤ 0.2%	0.05%
Impurity G	≤ 0.15%	ND
Each Unspecified Impurity	≤ 0.1%	Conforms
Total Impurities	≤ 0.3%	0.11%
Assay	98.5–101.0%	99.31%

Storage: Preserve in tightly closed, light-resistant containers below 30°C.

Conclusion: Material complies with EP11 specification.

Disclaimer: This document is a summary of information supplied by the original manufacturer and is provided for reference purposes only. Compounding Chemicals does not perform independent testing on every batch unless otherwise stated. Users are responsible for determining the suitability of the material for their intended application. Information is believed to be accurate at the time of issue but is not intended to replace the manufacturer's original Certificate of Analysis.