

Ketotifen Fumarate EP11

Batch no

20250503

Mf date

May 03 2025

Expiry

May 02 2028

Molecular Structure

Molecular Formula

C19H19NOS·C4H4O4

Molecular Weight

425.50

CAS Registry Number

34580-14-8

Jul 02 2025

<u>Tests</u>	Specifications	Results
Appearance Solubility	White to brownish-yellow, fine, crystalline powder Sparingly soluble in water, slightly soluble	Conforms Conforms
Identification Appearance of solution Sulfated ash	in methanol, very slightly soluble in acetone TLC, IR Clear & \leq Y ₄ , BY ₄ or B ₄ \leq 0.1%	Positive < BY ₄
Loss on drying (105°C, 4hr Related substances (HPLC)) ≤ 0.5%	0. 03% 0. 3%
Notated Substances (III Eo)	Impurity A ≤ 0.2% Impurity G ≤ 0.15% Each unspecified impurity ≤ 0.1%	0. 01% 0. 05% 0. 02%
Assay (odb)	Total impurities $\leq 0.3\%$ 98.5 ~ 101.0% of $C_{19}H_{19}NOS C_4H_4O_4$	0. 09% 99. 7%

Packaging & storage	Preserved in tight and light resistant container, temperature ≤ 30°C
Conclusion	Material complies with EP11