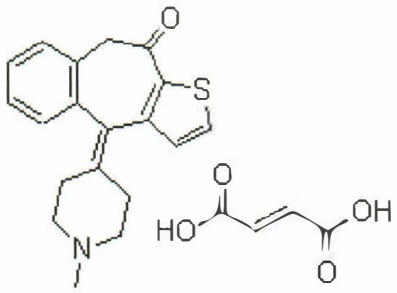
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Ketotifen Fumarate EP11

Batch no	20260720
Mf date	Jul 20 2026
Expiry	Jul 19 2029

Molecular Structure



Molecular Formula	$C_{19}H_{19}NOS \cdot C_4H_4O_4$
Molecular Weight	425.50
CAS Registry Number	34580-14-8

Oct 10 2026

Tests	Specifications		Results
Appearance	White to brownish-yellow, fine, crystalline powder		Conforms
Solubility	Sparingly soluble in water, slightly soluble in methanol, very slightly soluble in acetone		Conforms
Identification	TLC, IR		Positive
Appearance of solution	Clear & ≤ Y_4, BY_4 or B_4		< BY_4
Sulfated ash	≤ 0.1%		0.05%
Loss on drying (105℃, 4hr)	≤ 0.5%		0.12%
Related substances (HPLC)	Impurity A	≤ 0.2%	0.05%
	Impurity G	≤ 0.15%	ND
	Each unspecified impurity	≤ 0.1%	Conforms
	Total impurities	≤ 0.3%	0.12%
Assay (odb)	98.5 ~ 101.0% of $C_{19}H_{19}NOS \cdot C_4H_4O_4$		99.3%

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

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