

## Ketotifen Fumarate EP9

Batch no

20230919

Mf date

Sep 19 2023

Expiry

Sep 18 2026

Molecular Structure

Molecular Formula

 $C_{19}H_{19}NOS \cdot C_4H_4O_4$ 

Molecular Weight

425.50

CAS Registry Number

34580-14-8

Nov 15 2023

<u>Tests</u> <u>Specifications</u> <u>R</u>	Results
0.1.1.111	Conforms Conforms
	ositive
Appearance of solution Clear & $\leq Y_4$ , BY <sub>4</sub> or B <sub>4</sub> $<$	BY <sub>4</sub>
Sulfated ash $\leq 0.1\%$	. 05%
Loss on drying $(105^{\circ}C, 4hr) \le 0.5\%$	. 2%
Related substances (HPLC) Impurity A $\leq 0.2\%$	. 03%
Impurity G $\leq$ 0.2%	ID
Each unspecified impurity ≤ 0.1% C	onforms
Total impurities $\leq 0.3\%$	. 26%
Assay (odb) 98.5 $\sim$ 101.0% of $C_{19}H_{19}NOS \cdot C_4H_4O_4$ 9	9. 12%

Packaging & storage	Preserved in tight and light resistant container, temperature ≤ 30°C
Conclusion	Material complies with EP9

