

Loratadine USP39

Batch no

WT202501M01

Mf date Exp date Dec 27 2024 Dec 26 2027

2 23 21

Molecular Structure

Molecular Formula

 $C_{22}H_{23}CIN_2O_2$

Molecular Weight

382.88

CAS Registry Number

79794-75-5

Feb 20 2025

<u>Tests</u>	Specifications	Results
Appearance	White to off-white powder	Conforms
Solubility	Freely soluble in acetone, in chloroform, in methanol & in toluene; insoluble in water	Conforms
Identification	IR, RRT	Positive
Residue on ignition	≤ 0.1%	0. 03%
Heavy metals	≤ 10 ppm	< 10 ppm
Related substances	Fluoroloratadine ≤ 0.2%	ND
*	Unspecified impurities $\leq 0.1\%$	0. 01%
	Total impurities ≤ 0.3%	0. 02%
Loss on drying	≤ 0.5%	0. 12%
Microbial enumeration	Total aerobic microbial counts ≤ 1000 cfu/gr	< 10 cfu/gr
	Total molds & yeasts counts ≤ 100 cfu/gr	
Assay	98.5 ~ 101.0%	100.0%
Packaging and storage	Preserve in well-closed containers and store between 2 ~ 30°C	
Conclusion	Material complies with USP39	