

## Loratadine USP39

Batch no Mf date

WT202405M01 May 18 2024

Exp date

May 17 2026



Molecular Formula

 $C_{22}H_{23}CIN_2O_2$ 

Molecular Weight

382.88

CAS Registry Number 79794-75-5

Jul 29 2024

Tests	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. 02%
Heavy metals	≤ 10 ppm	< 10 ppm
Related substances	Fluoroloratadine ≤ 0.2%	ND
	Unspecified impurities ≤ 0.1%	0. 02%
	Total impurities ≤ 0.3%	0. 03%
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. 3%
Packaging and storage	Preserve in well-closed containers and store between 2 ~ 30°C	£
Conclusion	Material complies with USP39	