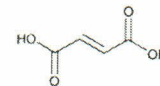
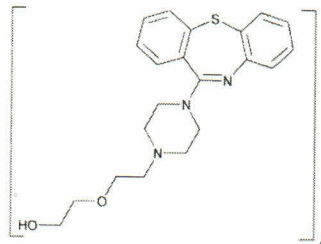


Quetiapine Fumarate USP

Batch no 5710-25-015
Mfg date Oct 09 2025
Retest date Oct 08 2030
Batch size 209.445 kgs

Molecular Structure



Molecular Formula $(C_{21}H_{25}N_3O_2S)_2 \cdot C_4H_4O_4$
Molecular Weight 883.09
CAS Registry Number 111974-72-2

Jan 06 2026

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White to off-white crystalline powder	White crystalline powder
Identification	IR, HPLC	Positive
Loss on drying	≤ 0.5%	< 0.1%
Residue on ignition	≤ 0.1%	< 0.1%
Related compounds (HPLC)	Quetiapine related compound G	≤ 0.15% < 0.01%
	Quetiapine related compound B	≤ 0.15% < 0.05%
	Quetiapine desethoxy	≤ 0.15% < 0.05%
	N-Ethyl quetiapine	≤ 0.15% ND
	Bis(dibenzopiperazinyl)piperazine	≤ 0.1% < 0.01%
	Quetiapine tetraethylene glycol analog	≤ 0.1% < 0.03%
	Any other unknown individual impurity	≤ 0.1% 0.05%
	Total impurities	≤ 0.5% 0.05%
Assay (HPLC) odb	98.0 ~ 102.0% of $(C_{21}H_{25}N_3O_2S)_2 \cdot C_4H_4O_4$	99.6%

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