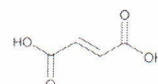
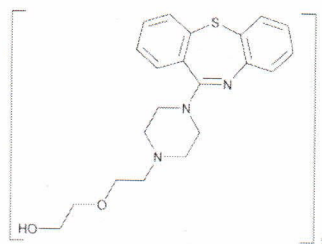


Quetiapine Fumarate USP

Batch no 5710-24-008
Mfg date Sep 20 2024
Retest date Sep 19 2029
Batch size 200.44 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

Oct 22 2024

<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%	0.2%
Residue on ignition	≤ 0.1%	< 0.1%
Related compounds (HPLC)	Quetiapine related compound G ≤ 0.15%	< 0.01%
	Quetiapine related compound B ≤ 0.15%	< 0.03%
	Quetiapine desethoxy ≤ 0.15%	< 0.05%
	N-Ethyl quetiapine ≤ 0.15%	< 0.03%
	Bis(dibenzopiperazinyl)piperazine ≤ 0.1%	ND
	Quetiapine tetraethylene glycol analog ≤ 0.10%	< 0.05%
	Any other unknown individual impurity ≤ 0.10%	< 0.03%
	Total impurities ≤ 0.50%	< 0.05%
Assay (HPLC) odb	98.0 ~ 102.0% of $(C_{21}H_{25}N_3O_2S)_2 \cdot C_4H_4O_4$	100.0%

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