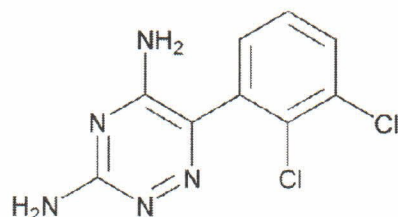


## Lamotrigine USP43

Batch no 009-220303  
 Mf date Mar 03 2022  
 Retest Sep 02 2026  
 Batch size 125.24 kg

### Molecular Structure



Molecular Formula  $C_9H_7Cl_2N_5$   
 Molecular Weight 256.09  
 CAS Registry Number 84057-84-1

Sep 09 2025

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	A white to pale cream-colored powder	A white powder
Solubility	Slightly soluble in 0.1 N hydrochloric acid, in acetone, in methanol; insoluble in water	Conforms
Identification	IR, RRT	Positive
Related compounds (HPLC)	Lamotrigine related compound C $\leq 0.1\%$ Lamotrigine related compound D $\leq 0.2\%$ Any individual unspecified impurity $\leq 0.1\%$ Total impurities $\leq 0.2\%$ (excluding Lamotrigine related compound B)	ND ND ND ND
Limit of Lamotrigine related compound B	$\leq 0.1\%$	ND
Loss on drying	$\leq 0.5\%$	0.03%
Residue on ignition	$\leq 0.1\%$	0.06%
Residual solvents (GC)	Ethanol $\leq 3000$ ppm	47 ppm
Assay (HPLC) odb	98.0 ~ 102.0% of $C_9H_7Cl_2N_5$	99.9%

Packaging and storage	Preserve in tight & light resistant container, temperature below 30°C
Conclusion	Material complies with USP43