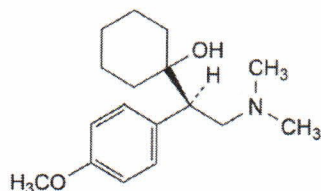


Batch no 102-20241001A
Mf date Oct 04 2024
Retest Oct 03 2026

Molecular Structure



and enantiomer, HCl

Molecular Formula $C_{17}H_{28}ClNO_2$
Molecular Weight 313.9
CAS Registry Number 99300-78-4

Nov 04 2024

Tests	Specifications	Results
Appearance	White or almost white powder	White powder
Solubility	Freely soluble in water & in methanol, soluble in anhydrous ethanol, slightly soluble or practically insoluble in acetone, Shows polymorphism	Conforms
Identification	IR, Chloride test	Positive
Acidity or alkalinity	0.01M sodium hydroxide \leq 0.2 mL	Conforms
Related substances	Impurity C \leq 0.1%	< 0.03%
	Impurity D \leq 0.1%	< 0.03%
	Impurity F \leq 0.1%	< 0.03%
	Impurity CHD \leq 0.1%	< 0.03%
	Max individual unknown impurity \leq 0.1%	< 0.03%
	Total impurities \leq 0.2%	0.0%
Residual solvents	Toluene \leq 890 ppm	2 ppm
	THF \leq 720 ppm	ND
	Ethyl acetate \leq 5000 ppm	ND
	Isopropanol \leq 5000 ppm	209 ppm
	Ethanol \leq 5000 ppm	ND
Loss on drying	\leq 0.5%	0.1%
Sulfated ash	\leq 0.1%	0.0%
Heavy metals	\leq 0.002%	< 0.002%
Assay (odb)	99.0 ~ 101.0% of $C_{17}H_{28}ClNO_2$	100.2%
Packaging & storage	Preserve in well-closed containers and store below 30°C	
Conclusion	Material complies with EP10.0	
Note	CHD:hydroxy cyclohexyl-4-methoxy phenyl acetonitrile	