

Sertraline HCI CP2020

Batch no Mf date Expiry

DK70-2401091 Jan 06 2024

Jan 05 2026

Molecular Structure

Molecular Formula

 $C_{17}H_{18}CI_3N$

Molecular Weight

342.7

CAS Registry Number

79559-97-0

Mar 20 2024

<u>Tests</u>	<u>Specifications</u>	Results
Appearance Identification Specific optical rotation	White powder or crystalline powder White HPLC, UV, IR, Reaction of chlorides +36 ~ +43°	te crystalline powder Positive +39.9°
Appearance of solution	Clear; not more intensely coloured than Y_2 or G	
Related substances	Impurity A ≤ 0.2%	0. 04%
	Impurity B ≤ 0.2%	< 0.02%
	Impurity C + D \leq 0.8%	0. 02%
	Impurity F ≤ 0.2%	< 0.02%
	Any other detectable impurity ≤ 0.1%	0.06% (RRT: 0.95)
		0. 06% (RRT:1, 2)
		0. 06% (RRT: 1. 3)
	Total impurities ≤ 1.5%	0. 33%
Impurity E	≤ 0.2%	< 0.02%
Isomers	≤ 1.0%	< 0.02%
Loss on drying	≤ 0.5%	0.06%
Residue on ignition	≤ 0.1%	0. 04%
Heavy metals	≤ 0.001%	< 0.001%
Residual solvents (GC)	Methanol $\leq 0.3\%$	< 0.003%
	Ethanol ≤ 0.5%	0. 0277%
	n-ButanoI ≤ 0.5%	< 0.005%
	Tetrahydrofuran ≤ 0.072%	< 0.0005%
	Ethyl acetate ≤ 0.5%	< 0.0005%
	Toluene ≤ 0.089%	< 0.0001%
	O-Dichlorobenzene ≤ 0.036%	< 0.001%
	N-Methyl formamide $\leq 0.088\%$	< 0.005%
Assay (odb)	\geq 98.5% of $C_{17}H_{17}CI_{2}N\cdot HCI$	99.4%
Packaging & storage	Protected from light, in well closed conta	iner
Conclusion	Material complies with CP2020	