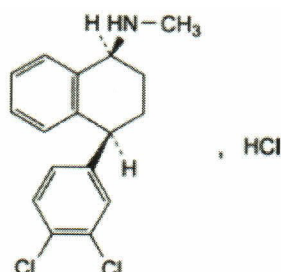


Batch no DK72-2603031  
Mf date Mar 03 2026  
Retest date Mar 02 2028  
Batch size 119.83 kg

Molecular Structure



Molecular Formula  $C_{17}H_{18}Cl_3N$

Molecular Weight 342.7

CAS Registry Number 79559-97-0

Jun 22 2026

| Tests                      | Specifications                                   | Results                              |
|----------------------------|--------------------------------------------------|--------------------------------------|
| Appearance                 | White or off-white crystalline powder            | White powder                         |
| Identification             | UV, IR, Reaction of chlorides                    | Positive                             |
| Related substances         | 2,3-Isosertraline $\leq 0.15\%$                  | $< 0.02\%$                           |
|                            | Impurity B $\leq 0.2\%$                          | $< 0.02\%$                           |
|                            | Impurity C $\leq 0.2\%$                          | 0.02%                                |
|                            | Impurity D $\leq 0.2\%$                          | $< 0.02\%$                           |
|                            | Impurity F $\leq 0.1\%$                          | $< 0.02\%$                           |
|                            | Any individual unspecified impurity $\leq 0.1\%$ | 0.02% (RRT:0.93)<br>0.03% (RRT:2.30) |
| Isomers                    | Total impurities $\leq 0.5\%$                    | 0.07%                                |
|                            | R,R-Sertraline HCl (Impurity G) $\leq 1.0\%$     | $< 0.02\%$                           |
|                            | R,S-Sertraline HCl (Impurity A) $\leq 0.1\%$     | $< 0.02\%$                           |
|                            | S,R-Sertraline HCl (Impurity A) $\leq 0.1\%$     | $< 0.02\%$                           |
|                            | Total isomers $\leq 1.0\%$                       | $< 0.02\%$                           |
| Mandelic acid (Impurity E) | $\leq 0.2\%$                                     | $< 0.02\%$                           |
| Loss on drying             | $\leq 0.5\%$                                     | 0.07%                                |
| Residue on ignition        | $\leq 0.1\%$                                     | 0.04%                                |
| Heavy metals               | $\leq 10$ ppm                                    | $< 10$ ppm                           |
| Residual solvents          | DMSO $\leq 5000$ ppm                             | $< 15$ ppm (DL)                      |
|                            | N-Methyl formamide $\leq 880$ ppm                | $< 26$ ppm (DL)                      |
|                            | Ethanol $\leq 5000$ ppm                          | 573 ppm                              |
|                            | n-Butanol $\leq 5000$ ppm                        | $< 45$ ppm (DL)                      |
|                            | Toluene $\leq 890$ ppm                           | $< 18$ ppm (QL)                      |
|                            | Chloroethane $\leq 1000$ ppm                     | 5 ppm                                |
| Assay (odb)                | 97.0 ~ 102.0% of $C_{17}H_{17}Cl_2N \cdot HCl$   | 100.2%                               |

|                     |                                   |
|---------------------|-----------------------------------|
| Packaging & storage | Preserve in well-closed container |
| Conclusion          | Material complies with ChP2025    |