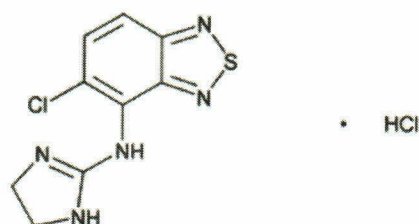


## Tizanidine HCl USP44

Batch no TZL/003/26  
Mf date Mar 2026  
Retest Feb 2031  
Batch size 120 kg

### Molecular Structure



Molecular Formula  $C_9H_8ClN_5S \cdot HCl$   
Molecular Weight 290.17  
CAS Registry Number 64461-82-1

Aug 12 2026

| Tests                     | Specifications                                                                                                                                                                                                          | Results                            |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Appearance                | Almost white to slightly yellow crystalline powder                                                                                                                                                                      | Slightly yellow crystalline powder |
| Solubility                | Slightly soluble in water and in methanol                                                                                                                                                                               | Conforms                           |
| Identification            | IR, HPLC<br>Gives reaction of chloride: It should be comply                                                                                                                                                             | Positive<br>Conforms               |
| pH (1% aqueous solution)  | 4.3 ~ 5.3                                                                                                                                                                                                               | 4.79                               |
| Related substances (HPLC) | Tizanidine related compound A $\leq 0.1\%$<br>Tizanidine related compound B $\leq 0.1\%$<br>Tizanidine related compound C $\leq 0.1\%$<br>Any individual unknown impurity $\leq 0.1\%$<br>Total impurities $\leq 0.3\%$ | ND<br>ND<br>ND<br>0.02%<br>0.02%   |
| Residue on ignition       | $\leq 0.1\%$                                                                                                                                                                                                            | 0.05%                              |
| Loss on drying            | $\leq 0.5\%$                                                                                                                                                                                                            | 0.23%                              |
| Assay (HPLC) odb          | 98.0 ~ 102.0%                                                                                                                                                                                                           | 100%                               |

|                       |                                                              |
|-----------------------|--------------------------------------------------------------|
| Packaging and storage | Preserve in tight containers, and store at room temperature. |
| Conclusion            | Material complies with USP44                                 |