

Estradiol Micronized USP43

Batch no

80806702502002

Mf date

Feb 10 2025

Retest

Feb 09 2029



Molecular Formula $C_{18}H_{24}O_2$

Molecular Weight 272.38

CAS Registry Number 50-28-2

Apr 17 2025

| Tests | Specifications | Results |
|---------------------|--|--------------------------|
| Appearance | White or off-white crystalline powder or colourless crystals | White crystalline powder |
| Solubility | Practically insoluble in water, soluble in alcohol, in acetone, in dioxane, in chloroform and in solutions of alkali hydroxides; | Conforms |
| | sparingly soluble in vegetable oils. | |
| Identification | IR | Positive |
| | Absorption at 280 nm ≤ 3.0% (oab) | 0. 2% |
| Melting range | 173 ~ 179°C | 177.5 ~ 178.5°C |
| Specific rotation | +76 ~ +83° | +80. 2° |
| Water | ≤ 3.5% | 3. 3% |
| Related substances | Any individual impurity ≤ 0.5% | RRT 0.87: 0.1% |
| | | RRT 1.17: 0.06% |
| 2 3. | Total impurities ≤ 1.0% | 0. 17% |
| Residue on ignition | ≤ 0.1% | 0.06% |
| Residual solvents | Methanol ≤ 3000 ppm | ND |
| | Ethanol ≤ 5000 ppm | 506 ppm |
| | Acetone ≤ 5000 ppm | ND |
| | Acetic acid ≤ 5000 ppm | ND |
| Particle size | d(0.9) < 10 um | Conforms |
| Assay (oab) | 97.0 $^{\sim}$ 103.0% of $C_{18}H_{24}O_2$ | 99. 4% |
| Packaging & storage | Preserve in tight, light-resistant containe Store at 25°C, excursions permitted between | |
| Conclusion | Material complies with USP43 | |