

## Ethinyl Estradiol USP43

Batch no

73804402405002

Mf date

May 05 2024 May 04 2026

Retest Batch size

19:32 kg

Molecular Structure

Molecular Formula

 $C_{20}H_{24}O_2$ 

Molecular Weight 296.40

CAS Registry Number 57-63-6

May 13 2024

| Tests  | Specifications  | Results  |
|--|---|--|
| Appearance   | White or slightly yellowish-white crystalline powder  | Conforms   |
| Identification   | IR  | Positive   |
| Melting point Specific optical rotation Clarity of solution Loss on drying Residual solvents | Absorptivities at 281nm ≤ 3.0% 180 ~ 186°C +28.0 ~ +29.5° It should be clarified & no insoluble solid ≤ 1.0% Acetone ≤ 5000 ppm Ethanol | 0<br>181 ~ 184°C<br>+29.1°<br>Conforms<br>0.22%<br>236 ppm |
| 5  | Ethanol ≤ 5000 ppm<br>Tetrahydrofuran ≤ 720 ppm   | ND<br>ND   |
| Particle size  | d(0.9) < 10 µm  | Conforms   |
| Assay (odb)  | 97.0 $^{\sim}$ 102.0% of $C_{20}H_{24}O_2$  | 99.9%  |
|  |   |  |

| Packaging & storage | Preserve in tight, nonmetallic, light-resistant containers |
|---------------------|--|
| Conclusion          | Material complies with USP43                               |