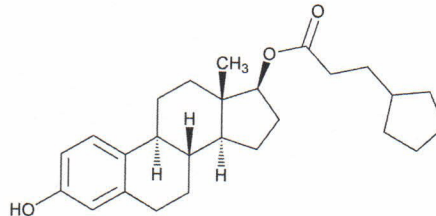


Batch no 240101
Mf date Jan 15 2024
Expiry Jan 14 2028
Batch size 35.07 kg

Molecular Structure



Molecular Formula $C_{26}H_{36}O_3$
Molecular Weight 396.56
CAS Registry Number 313-06-4

Sep 04 2024

| <u>Tests</u> | <u>Specifications</u> | <u>Results</u> |
|---------------------------|---|-----------------|
| Appearance | White powder | Conforms |
| Solubility | Soluble in alcohol, in acetone, in chloroform, and in dioxane; sparingly soluble in vegetable oils; insoluble in water. | Conforms |
| Identification | IR, UV | Positive |
| Melting range | 149 ~ 153°C | 151.1 ~ 152.3°C |
| Specific optical rotation | +39 ~ +44° | +39.9° |
| Loss on drying | ≤ 1.0% | 0.08% |
| Residue on ignition | ≤ 0.2% | 0.11% |
| Related substances | Estradiol ≤ 0.15% | 0.02% |
| | Estradiol-9-ene cypionate ≤ 0.15% | 0.08% |
| | 4-Meylestradiol cypionate ≤ 0.15% | Conforms |
| | Estradiol dicyponate ≤ 0.15% | 0.03% |
| | Unspecified impurities ≤ 0.1% | 0.09% |
| Residual solvents | Methanol ≤ 3000 ppm | 21.24 ppm |
| | Ethyl acetate ≤ 5000 ppm | 49.06 ppm |
| | Toluene ≤ 890 ppm | 15.7 ppm |
| | Ethanol ≤ 5000 ppm | 89.52 ppm |
| | Heptane ≤ 5000 ppm | 71.51 ppm |
| Particle size | ---- | 90% ≤ 20 μm |
| Assay | 97.0 ~ 103.0% of $C_{23}H_{32}O_3$ | 99.7% |

| | |
|---------------------|---|
| Packaging & storage | Preserve in tight, light-resistant containers |
| Conclusion | Material complies with USP41 |