



Certificate of analysis

Product name: DL-Cloprostenol sodium

Cas number: 55028-72-3

Molecular Formula: $C_{22}H_{28}ClNaO_6$

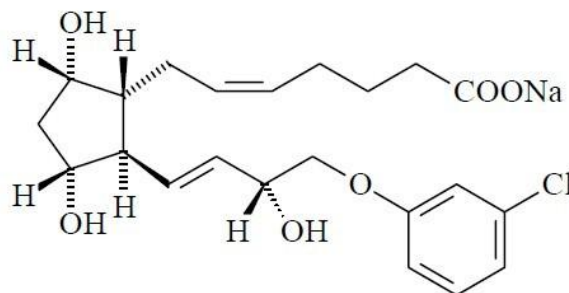
Molecular Weight: 446.90

Date of production: Oct. 18, 2024

Batch NO: 20241018

EXP DATE: Oct. 17, 2026

Chemical structure:



| Items | Specifications | Results |
|------------------------|--|---|
| Appearance | A white or almost white, amorphous powder; hygroscopic | Conform |
| Identification | HPLC White precipitate is observed in characteristic testing of sodium salts | Conform |
| Water content | $\leq 3.0\%$ | 1.1% |
| 15-epimer | $\leq 1.0\%$ | Not detected |
| 5,6-trans isomer | $\leq 1.0\%$ | 0.07% |
| Individual impurity | $\leq 1.0\%$ | 0.08% |
| Total impurities | $\leq 2.5\%$ | 0.04% |
| Residual solvents | Toluene $\leq 0.089\%$ Methanol $\leq 0.3\%$ n-Hexane $\leq 0.029\%$ Acetone $\leq 0.5\%$ Tert-Butyl methyl ether $\leq 0.5\%$ Ethyl acetate $\leq 0.5\%$ Total residual solvents $\leq 0.3\%$ | Not detected Not detected Not detected Not detected Not detected 0.05% 0.136% |
| Microbiological purity | TAMC $\leq 10^2$ cfu/g | Conform |
| | TYMC ≤ 10 cfu/g | Conform |
| | Staphylococcus aureus Not allowed/1g | Conform |
| | Pseudomonas aeruginosa Not allowed/1g | Conform |
| | bile-tolerant Enterobacteriaceae Not allowed/1g | Conform |
| Assay | 97.5%~101.0% (calculated on the anhydrous basis) | 99.80% |

Conclusion: Complies with USP43 standard.