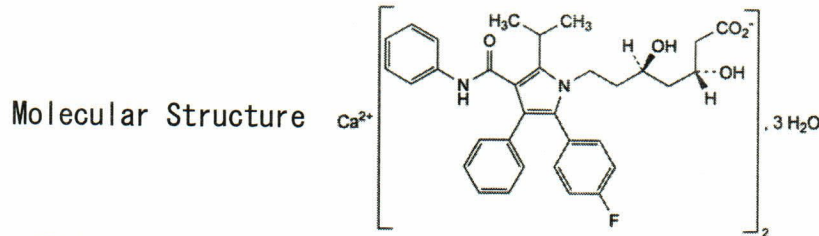




Batch no FP281202602001
Mf date Feb 05 2026
Retest Feb 04 2028



Molecular Formula C₆₆H₆₈CaF₂N₄O₁₀ · 3H₂O
Molecular Weight 1209.42
CAS Registry Number 344423-98-9

Apr 03 2026

Tests	Specifications	Results
Appearance	White or off-white powder	White powder
Solubility	Soluble to freely soluble in methanol; slightly soluble in alcohol; insoluble to very slightly soluble in distilled water, in pH 7.4 phosphate buffer & in acetonitrile, insoluble in aqueous solutions of pH 4 and below	Conforms
Identification	IR, Calcium	Positive
Elemental impurity	Cd ≤ 0.5 ppm Pb ≤ 0.5 ppm As ≤ 1.5 ppm Hg ≤ 3 ppm Ni ≤ 20 ppm Mo ≤ 300 ppm	0.003% < 0.02% < 0.0006% < 0.01% 0.03% < 0.07%
Enantiomeric purity HPLC (Impurity E)	≤ 0.3%	< 0.02%
Related substances	Impurity A ≤ 0.3% Impurity B ≤ 0.3% Impurity C ≤ 0.3% Impurity D ≤ 0.2% Any unspecified impurity ≤ 0.1% Total impurities ≤ 1.0%	0.03% < 0.02% < 0.03% < 0.01% 0.03% 0.2%
Water	3.5 ~ 5.5%	4.6%
Residual solvents	Ethanol ≤ 5000 ppm Toluene ≤ 890 ppm n-Hexane ≤ 290 ppm	< 28 ppm 29 ppm 12 ppm
Assay (oab) HPLC	98.0 ~ 102.0% of C ₆₆ H ₆₈ CaF ₂ N ₄ O ₁₀	99.7%

Packaging & storage	Preserve in tight containers, light-resistant, store at room temperature, keep in dry place
Conclusion	Material complies with USP2024