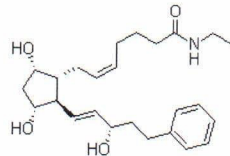




Bimatoprost

Batch no 2401001
Mf date Jan 09 2024
Retest Jan 08 2026

Molecular Structure



Molecular Formula $C_{25}H_{37}NO_4$
Molecular Weight 415.57
CAS Registry Number 155206-00-1

Mar 07 2024

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Description	White or almost white crystalline powder	White powder
Identification	IR	Positive
Melting point	60 ~ 70°C	66.2°C
Optical rotation $[\alpha]_D^{20}$	+30.0 ~ +36.0° (c=1.0, CH ₃ CN)	+35.8°
Water content (KF)	≤ 1.0%	0.18%
Heavy metals	≤ 20 ppm	Conforms
Sulphated ash	≤ 0.2%	0.1%
Related substances	15- <i>epi</i> -Bimatoprost ≤ 0.15%	ND
	5,6- <i>trans</i> Bimatoprost ≤ 0.3%	0.09%
	Any other single impurity ≤ 0.1%	0.02%
	Total impurities ≤ 1.0%	0.12%
	Residual solvents	Methanol ≤ 3000 ppm
Ethanol ≤ 5000 ppm		ND
Acetone ≤ 5000 ppm		ND
Dichloromethane ≤ 600 ppm		ND
<i>tert</i> -Butylmethyl ether ≤ 5000 ppm		1059 ppm
Ethyl acetate ≤ 5000 ppm		109 ppm
Toluene ≤ 890 ppm		ND
Assay (oab, solvent-free basis)	97.5 ~ 101.0% of $C_{25}H_{37}NO_4$	99.88%

Packaging & storage	Preserve at ambient temperature & in well-closed containers
Conclusion	Material complies with in-house standard