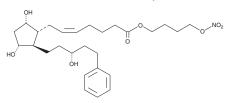
# Ophthalmology APIs

The natural compound prostaglandin  $F_{2\alpha}$  (PGF $_{2\alpha}$ ) activates signaling pathways in the eye that reduce intraocular pressure (IOP). A family of PGF $_{2\alpha}$  analogs, including bimatoprost, latanoprost, tafluprost, and travoprost, have been developed, and these compounds are more potent than PGF $_{2\alpha}$  itself in lowering IOP and have fewer side effects. Moreover, they are known to be safe and effective when used in the treatment of glaucoma.

- · US FDA and EMA compliant
- Analytical standards of impurities and degradation products available

# CGMP Latanoprostene Bunod



#### Nomenclature

Formal Name: (5Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]

5-heptenoic acid, 4-(nitrooxy)butyl ester

CAS Number: 860005-21-6

#### Formula

Molecular Formula: C<sub>27</sub>H<sub>41</sub>NO<sub>8</sub> · Formula Weight: 507.6

## Physiochemical Data

Solubility: Very soluble in acetone, ethanol, ethyl acetate, and chloroform

Appearance: Colorless to slightly yellow oil

**Optical Rotation:**  $[\alpha]_D^{20} = +27^{\circ} \text{ to } +32^{\circ} \text{ (CH}_3\text{CN, c} = 10 \text{ mg/ml, } 589 \text{ nm)}$ 

## Availability

GMP material is available, and the DMF for Latanoprostene Bunod is available for customer review upon request. The DMF has been filed with the US FDA.



## **CGMP Tafluprost**

#### Nomenclature

Formal Name: 15,15-difluoro-9α,11α-dihydroxy-16-phenoxy-17,18,19,20-tetranor-prosta-5Z,13E-dien-1-oic acid, isopropyl ester

CAS Number: 209860-87-7

#### Formula

Molecular Formula:  $C_{25}H_{34}F_2O_5$  · Formula Weight: 452.5

#### Physiochemical Data

Solubility: Very soluble in acetone, acetonitrile, dichloromethane, diethylether, ethanol, methanol; practically insoluble in water

and n-heptane

Appearance: Clear, colorless to slightly yellow oil

**Optical Rotation:**  $[\alpha]_{D}^{20} = +24.0^{\circ} \text{ to } +29.0^{\circ} \text{ (CH}_{3}\text{CN, c} = 10 \text{ mg/ml})$ 

#### Availability

GMP material is available, and the DMF for Tafluprost is available for customer review upon request. The DMF has been filed with the US FDA and in Russia.

## **CGMP** Bimatoprost

#### Nomenclature

Formal Name: N-ethyl-9α,11α,15S-trihydroxy-17-phenyl-18,19,20-trinor-prosta-5Z,13E-dien-1-amide

CAS Number: 155206-00-1

#### Formula

Molecular Formula:  $C_{25}H_{37}NO_4$  · Formula Weight: 415.6

## Physiochemical Data

**Solubility:** Very soluble in ethanol, methanol, dimethyl formamide, and DMSO; freely soluble in acetone; soluble in diethylene glycol; sparingly soluble in ethyl acetate; slightly soluble in water; insoluble in heptane

Appearance: White to slightly off-white crystalline powder

**Optical Rotation:**  $[\alpha]_D^{20} = +31.0^{\circ} \text{ to } +37.0^{\circ} \text{ (CH}_3\text{CN, c} = 1,589 \text{ nm)}$ 

## Availability

GMP material is available, and the DMF for Bimatoprost is on file with the US FDA, Canada, and India.

## **CGMP** Latanoprost

#### Nomenclature

Formal Name: 9α,11α,15R-trihydroxy-17-phenyl-18,19,20-trinor-prost-5Z-en-1-oic acid, isopropyl ester

CAS Number: 130209-82-4

Formula

Molecular Formula:  $C_{26}H_{40}O_5$  · Formula Weight: 432.6

Physiochemical Data

Solubility: Very soluble in ethanol, chloroform, acetonitrile, and DMSO; slightly soluble in water

Appearance: Clear, thick, colorless to slightly yellow oil

**Optical Rotation:** [ $\alpha$ ]<sub>D</sub><sup>20</sup> = +33.5° to +37.0° (CH<sub>3</sub>CN, c = 0.91, 589 nm)

Availability

GMP material from both Cayman Chemical and Cayman Pharma, which conforms to the USP, EP, and IP Monographs, is available. Each site maintains a unique DMF; they have been filed with the US FDA, Canada, India, several EU member states, and several other countries. Cayman Chemical GMP material has been granted a Certificate of Suitability (CEP) as of 28 August 2023.

# **CGMP** Travoprost

#### Nomenclature

Formal Name: (+)-9α,11α,15R-trihydroxy-16-(3-(trifluoromethyl)phenoxy)-17,18,19,20-tetranor-prosta-5Z,13E-dien-1-oic acid,

isopropyl ester

CAS Number: 157283-68-6

Formula

Molecular Formula:  $C_{26}H_{35}F_{3}O_{6}$  · Formula Weight: 500.6

Physiochemical Data

Solubility: Very soluble in ethanol, methanol, chloroform, dichloromethane, and acetonitrile; practically insoluble in water

Appearance: Clear, colorless to slightly yellow oil

Optical Rotation:  $[\alpha]_D^{20} = +14.6^{\circ} (CH_2CI_2, c = 10 \text{ mg/ml})$ 

Availability

GMP material, which conforms to the USP Monograph, is available. The DMF is on file with the US FDA, Canada, India, Japan, China, several EU member states, and several other countries.