



## TECHNICAL DATA SHEET

012439-TDS-ENG-2021

BIMATOPROST		
DESCRIPTION DCI: BIMATOPROST		DESCRIPTION DOE: BIMATOPROST
CAS N°: 155206-00-1	EC N°: 642-890-9	AEMPS CODE: ---
MOL. WEIGHT: 415.57	MOL. FORMULA: C <sub>25</sub> H <sub>37</sub> NO <sub>4</sub>	ARTICLE CODE: 012439

ATTRIBUTES	SHOULD BE
Appearance	White to slightly off-white crystalline powder
Solubility	Very soluble in acetone, ethanol, methanol, dimethyl sulfoxide, soluble in acetonitrile, sparingly soluble in ethyl acetate, slightly soluble in water
Identification IR	Complies
Identification HPLC	Complies
Assay	98.0 - 102.0 %
Purity	
N-hydroxysuccinimide	=< 0.15 %
5,6-trans Bimatoprost	=< 0.15 %
15(R)-Bimatoprost	=< 0.15 %
Free Acid Bimatoprost	=< 0.15 %
Bimatoprost Cyclohexylamide	=< 0.15 %
15-keto Bimatoprost	=< 0.15 %
Triphenylphosphine Oxide	=< 0.15 %
Other single impurities	=< 0.10 %
Total impurities	=< 1.0 %
Optical rotation	+33.0° / +37.0°
Water	=< 1.0 %
Residue on ignition	=< 0.10 %
Residual solvents	
Methylene Chloride	=< 600 ppm
Ethyl acetate	=< 5000 ppm
n-Heptane	=< 2500 ppm
Acetone	=< 5000 ppm
Toluene	=< 890 ppm
Methyl tert-butyl ether	=< 5000 ppm
Methanol	=< 3000 ppm
Tetrahydrofuran	=< 720 ppm
Benzene	=< 2 ppm
Elemental impurities	
Arsenic	=< 0.15 µg/g
Boron	=< 50 µg/g
Cadmium	=< 2.5 µg/g
Lead	=< 0.5 µg/g
Mercury	=< 1.5 µg/g
Microbiological control	
TAMC	=< 100 CFU/g



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TYMC

= < 10 CFU/g

### COMPLIES WITH

Manufacturer Specifications

### STORAGE

Store in a dark, dry place at a temperature -20 ± 5 °C.

### REMARKS

Bimatoprost is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.