METAPHARMACEUTICAL

N DE LOTE: 0031122

02/11/2022

Cayman Pharma s.r.o.
ul. Práce 657, 277 11 NERATOVICE
CZECH REPUBLIC
Tel. +420 313 033 155

CERTIFICATE OF QUALITY

No.:2210B096

PRODUCT: **LATANOPROST**

5-Heptenoic acid, 7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-, 1-methylethyl ester, (5Z)-

$C_{26}H_{40}O_5$ = 432.6

CAS - 130209-82-4

BATCH No.: 2210S002

PRODUCTION DATE: 10/2022

ATEST No.: A220210

RE-TEST DATE: 10/2025

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) FTIR spectrum	NLT 90 % IR conformity to spectrum of RS	94 %
b) HPLC retention time	K = 0.90 – 1.10	1.00
2. Visual appearance	colorless to yellow oil	colorless oil
3. Assay by HPLC (anhydrous basis)	96.0 – 102.0 %	98.8 %
4. Purity by HPLC		
a) 5-*trans*-Latanoprost	NMT 2.0 %	1.1 %
b) (15*S*)-Latanoprost	NMT 0.15 %	not detected
c) *15-keto*-Latanoprost	NMT 0.15 %	not detected
d) Triphenylphosphine oxide	NMT 0.15 %	not detected
e) Latanoprost free acid	NMT 0.15 %	not detected
f) Isopropyldiphenylphosphoryl pentanoate	NMT 0.1 %	not detected
g) Other impurities single	NMT 0.1 %	not detected
h) Impurities total [c) to g)]	NMT 0.5 %	not detected
5. spec. optical rotation (c=10 mg/mL, acetonitrile) $[\alpha]_D^{20}$	+32.0° to +38.0°	+34.5°
6. Water (KF)	NMT 0.5 %	< 0.3 %
7. Residue on ignition	NMT 0.50 %	0.05 %

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TEST METHOD:	SPECIFICATION:	RESULT:
8. Residual solvents content (GC)		
a) Acetone	NMT 1000 ppm	not detected
b) Propan-2-ol	NMT 1000 ppm	not detected
c) Dichloromethane	NMT 600 ppm	not detected
d) *n*-Heptane	NMT 1000 ppm	< 1000 ppm
e) Ethyl acetate	NMT 1000 ppm	not detected
f) Tetrahydrofuran	NMT 200 ppm	not detected
g) Toluene	NMT 250 ppm	not detected
h) *tert.*-Butyl Methyl Ether	NMT 300 ppm	not detected
i) *N,N'*-Dimethylformamide	NMT 880 ppm	not detected
9. Microbial testing (CFU / g)		
Total aerobic microbial count	NMT 10^3 (2000) CFU/g	< 10 CFU/g
Total yeasts & moulds count	NMT 10^2 (200) CFU/g	< 10 CFU/g

RESULT: Product has been manufactured in accordance with principles of GMP as detailed in ICH Guideline Q7.
Product conforms to the specification in valid version SBR387K, App. No. 1
Product conforms to the specification in USP 44 and Microbial testing of the product conforms to the specification in Ph. Eur. 10., harmonised method.

Ing. Dagmar Goldšmídová
Authorized Person
(pursuant to EudraLex 4/II, §2.14 & §2.32.1)

AUTHORIZED PERSON * OPRÁVNĚNÁ OSOBA
Cayman Pharma s.r.o.
QA
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Date: Oct. 24, 2022