METAPHARMACEUTICAL

N DE LOTE: 0121121

10/11/2021

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

CERTIFICATE OF QUALITY

No.:2109B094

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.: 2105S003

PRODUCTION DATE: 05/2021

ATEST No.: A210107

RE-TEST DATE: 05/2024

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) FTIR spectrum	NLT 90 % IR conformity to spectrum of RS	96 %
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 %	99.3 %
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°	+34.8°
6. Water (KF)	NMT 0.5 %	< 0.3 %
7. Residue on ignition	NMT 0.50 %	< 0.02 %

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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	not detected
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 Q7A
Product conforms to the specification in valid version SBR387K, App. No. 1
Product conforms to the specification in USP 43 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)

Date: Sep. 20, 2021