Cayman Pharma s.r.o.
ul. Práce 657, 277 11 NERATOVICE
CZECH REPUBLIC
Tel. +420 315 665 360

CERTIFICATE OF QUALITY

No.: 2002D039

CUSTOMER: A.C.E.F. SPA

PRODUCT: **ALPROSTADIL**
7-{(1R,2R,3R*)-3-Hydroxy-2-[€-(3S)-3-hydroxy-1-octenyl]-5-oxocyclo-pentyl}-heptanoic acid
$C_{20}H_{34}O_5$ = 354.5
CAS – 745-65-3

BATCH No.: 1805S001

PRODUCTION DATE: 05/2018

ATEST No.: A180157

QUANTITY: 1.0 g

RETEST DATE: 05/2021

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) by IR spectrum	IR spectrum conforms with IR of RS Ph.Eur.	IR spectrum conforms
b) by RT WS HPLC	K = 0.90 – 1.10 RT of RS	1.00
2. Appearance		
a) visual	a white or off-white crystalline material	a white crystalline material
b) by absorbance	the sum of absorbance NMT 0.150	0.004
3. Assay (HPLC, calculated with reference to anhydrous substance, abs. %):	96.0 - 102.5 % *	99.2 %
4. HPLC purity (Ph.Eur. HPLC method, norm. %):		
a) PGA_1	NMT 1.3 %	< 0.1 %
b) PGB_1	NMT 0.1 %	not detected
other impurities		
c) 15-keto-PGE_1	NMT 0.1 %	not detected
d) 15(R)-PGE_1	NMT 0.1 %	not detected
e) 11(β)-PGE_1	NMT 0.5 %	not detected
f) 8-iso-PGE_1	NMT 0.1 %	not detected
g) PGE_2	NMT 0.5 %	not detected
h) 5-trans-PGE_2	NMT 0.5 %	not detected
i) PGE_1 ethylester	NMT 0.3 %	not detected

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j) PGE_1 isopropylester	NMT 0.3 %	not detected
k) TPPO	NMT 0.5 %	not detected
l) unspecified impurities single	NMT 0.10 %	0.05 %
m) impurities total	NMT 1.5 %	0.1 %
5. HPLC purity (in-house HPLC method, mol. %):		
a) 14-methyl-PGE_1	NMT 0.15 %	not detected
b) PGD_1	NMT 0.1 %	not detected
c) 4-trans-PGE_2	NMT 0.15 %	not detected
d) 6-trans-PGE_2	NMT 0.15 %	0.12 %
e) 13,14-dihydro-PGE_1	NMT 0.15 %	not detected
f) unspecified impurities single	NMT 0.10 %	0.05 %
6. Water content	NMT 0.5 %	0.1 %
7. Residue on ignition	NMT 0.5 %	0.1 %
8. Spec. optic rotation (c=1, ethanol) $[\alpha]_D^{20}$	-70.0° to -60.0°	- 67.2°
9. Content of solvents (USP GC method):		
a) Acetone	NMT 0.5 %	< 0.5 %
b) Chloroform	NMT 10 ppm	not detected
c) *n*-Hexane	NMT 290 ppm	< 290 ppm
d) Dichloromethane	NMT 5 ppm	not detected
e) Tetrahydrofurane	NMT 10 ppm	not detected
f) Ethyl acetate	NMT 300 ppm	not detected
g) *tert.* Butyl methyl ether	NMT 300 ppm	not detected
h) Methyl alcohol	NMT 300 ppm	not detected
i) Isopropyl alcohol	NMT 300 ppm	not detected
j) *n*-Heptane	NMT 300 ppm	not detected
k) Toluene	NMT 20 ppm	not detected
l) *n*-Pentane	NMT 300 ppm	< 300 ppm
11. Heavy metals:		
a) rhodium content	NMT 20 ppm	9 ppm
b) chromium content	NMT 20 ppm	< 1 ppm

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TEST METHOD:	SPECIFICATION:	RESULT:
12. Microbial testing (CFU/g):		
Total aerobic microbial count	NMT 10^2 ($2x10^2$) CFU/g	<100 CFU/g
Total yeasts & moulds count	NMT 10^1 ($2x10^1$) CFU/g	< 10 CFU/g
Specific microorganisms:		
- Bile-tolerant G^- bacteria	0 CFU/g	not found
- Salmonella sp.	0 CFU/g	not found
- Escherichia coli	0 CFU/g	not found
- Staphylococcus aureus	0 CFU/g	not found
- Pseudomonas aeruginosa	0 CFU/g	not found

* 95.0 - 102.5 % at re-testing

RESULT: Product has been manufactured in accordance with principles of GMP as detailed in ICH Guideline Q7A
Product conforms to the specification in SBR380K/06, App. No. 2
Note: Product conforms to the specification in Ph. Eur. 10 and Microbial testing of product conforms to the specification in Ph. Eur. 10, harmonised method.

AUTHORIZED PERSON * OPRÁVNĚNÁ OSOBA
Cayman Pharma s.r.o.
QA
1

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

Date: Feb 13, 2020