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

# CERTIFICATE OF QUALITY

No.: 

**CUSTOMER:**

**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.:**

**PRODUCTION DATE:**

**ATEST No.**:

**QUANTITY:**

**RE-TEST DATE:**

| TEST METHOD: | SPECIFICATION: | RESULT: |
|---|---|---|
| 1. Identification | | |
| a) by IR spectrum | IR spectrum of CRS Eur.Ph. | |
| b) by RT WS HPLC | RT of WS HPLC | |
| 2. Appearance | | |
| a) visual evaluation | a white to off white crystalline material | |
| b) spectrophotometric evaluation | the sum of absorbance NMT 0.150 | |
| 3. Assay (HPLC, calculated with reference to anhydrous substance, abs. %): | 96.0 - 102.5 % * | |
| 4. HPLC purity (Ph.Eur. HPLC method, norm. %): | | |
| a) $PGA_1$ | NMT 1.3 % | |
| b) $PGB_1$ | NMT 0.1 % | |
| other impurities | | |
| c) 15-keto-$PGE_1$ | NMT 0.1 % | |
| d) 15(R)-$PGE_1$ | NMT 0.1 % | |
| e) 11(β)-$PGE_1$ | NMT 0.5 % | |
| f) 8-iso-$PGE_1$ | NMT 0.1 % | |
| g) $PGE_2$ | NMT 0.5 % | |
| h) 5-trans-$PGE_2$ | NMT 0.5 % | |
| i) $PGE_1$ ethylester | NMT 0.3 % | |

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|---|---|---|
| j) $PGE_1$ isopropylester | NMT 0.3 % | |
| k) TPPO | NMT 0.5 % | |
| l) unspecified impurities single | NMT 0.10 % | |
| m) impurities total | NMT 1.5 % | |
| 5. HPLC purity (in-house HPLC method, mol. %): | | |
| a) 14-methyl-$PGE_1$ | NMT 0.15 % | |
| b) $PGD_1$ | NMT 0.1 % | |
| c) 4-trans-$PGE_2$ | NMT 0.15 % | |
| d) 6-trans-$PGE_2$ | NMT 0.15 % | |
| e) 13,14-dihydro-$PGE_1$ | NMT 0.15 % | |
| f) unspecified impurities single | NMT 0.10 % | |
| 6. Water content | NMT 0.5 % | |
| 7. Residue on ignition | NMT 0.5 % | |
| 8. Spec. optic rotation (c=1, ethanol) $[\alpha]_D^{20}$ | -70.0° to -60.0° | |
| 9. Content of solvents (USP GC method): | | |
| a) Acetone | NMT 0.5 % | |
| b) Chloroform | NMT 10 ppm | |
| c) *n*-Hexane | NMT 290 ppm | |
| *d)* Dichloromethane | NMT 5 ppm | |
| e) Tetrahydrofurane | NMT 10 ppm | |
| f) Ethyl acetate | NMT 300 ppm | |
| g) *tert.* Butyl methyl ether | NMT 300 ppm | |
| h) Methyl alcohol | NMT 300 ppm | |
| i) *tert.* butyl alcohol | NMT 300 ppm | |
| j) Isopropyl alcohol | NMT 300 ppm | |
| k) *n*-Heptane | NMT 300 ppm | |
| *l)* Toluene | NMT 20 ppm | |
| m) *n*-Pentane | NMT 300 ppm | |

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| TEST METHOD: | SPECIFICATION: | RESULT: |
|---|---|---|
| 11. Heavy metals: | | |
| a) Rhodium content | NMT 20 ppm | |
| b) Chromium content | NMT 20 ppm | |
| 12. Microbial testing (CFU/g): | | |
| Total aerobic microbial count | NMT $10^2$ ($2x10^2$) CFU/1g | |
| Total yeasts & moulds count | NMT $10^1$ ($2x10^1$) CFU/1g | |
| Specific microorganisms: | | |
| - Bile-tolerant $G^-$ bacteria | 0 CFU/1 g | |
| - Salmonella sp. | 0 CFU/1 g | |
| - Escherichia coli | 0 CFU/1 g | |
| - Staphylococcus aureus | 0 CFU/1 g | |
| - Pseudomonas aeruginosa | 0 CFU/1 g | |

* 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/04, App. No. 2**
**Note: Product conforms to the specification in Ph. Eur. 7. and Microbial testing of product conforms to the specification in Ph. Eur. 7, harmonised method**



Authorized Person
(pursuant to EudraLex 4/II, §2.14 & §2.32.1)

Date: