



CERTIFICATE OF QUALITY

No.:

page 1 of 3

CUSTOMER:

PRODUCT:

ALPROSTADIL

7-((1R,2R,3R*)-3-Hydroxy-2-[(E)-(3S)-3-hydroxy-1-octenyl]-5-oxocyclopentyl)-heptanoic acid

$C_{20}H_{34}O_5 = 354.5$

CAS - 745-65-3

NDC # :

061556-010-00

BATCH No.:

PRODUCTION DATE:

ATEST No.:

QUANTITY:

RE-TEST DATE:

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) by IR spectrum	IR spectrum of CRS	
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 (USP HPLC method):		
Test 1		
a) PGA_1 (abs. %)	NMT 1.3 %	
b) PGB_1 (abs. %)	NMT 0.1 %	
c) impurity with RRT 0.6 (PGA_1) (norm. %)	NMT 0.9 %	
other impurities single (norm. %)	NMT 0.9 %	
Test 2		
d) Σ impurities with RRT 2.0 and 2.3 (PGE_1) (norm. %)	NMT 0.6 %	
e) other impurities single (norm. %)	NMT 0.9 %	
f) impurities total (Test 1 and Test 2) (norm. %)	NMT 2.0 %	

CERTIFICATE OF QUALITY

No.:

page 2 of 3

TEST METHOD:	SPECIFICATION:	RESULT:
5. HPLC purity (in-house HPLC method, mol. %):		
a) 14-methyl-PGE ₁	NMT 0.5 %	
b) 15R-PGE ₁	NMT 0.1 %	
c) 4-trans-PGE ₂	NMT 0.5 %	
d) 5-trans-PGE ₂	NMT 0.5 %	
e) 6-trans-PGE ₂	NMT 0.5 %	
f) PGD ₁	NMT 0.1 %	
g) 13,14-dihydro-PGE ₁	NMT 0.5 %	
h) other impurities single	NMT 0.1 %	
i) impurities total	NMT 2.0 %	
6. Water content		
	NMT 0.5 %	
7. Residue on ignition		
	NMT 0.5 %	
8. Spec. optic rotation (c=0.5, 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) <i>n</i> -Hexane	NMT 290 ppm	
d) Dichloromethane	NMT 5 ppm	
e) Tetrahydrofuran	NMT 10 ppm	
f) Ethyl acetate	NMT 300 ppm	
g) <i>tert.</i> Butyl methyl ether	NMT 300 ppm	
h) Methyl alcohol	NMT 300 ppm	
i) <i>tert.</i> Butyl alcohol	NMT 300 ppm	
j) Isopropyl alcohol	NMT 300 ppm	
k) <i>n</i> -Heptane	NMT 300 ppm	
l) Toluene	NMT 20 ppm	
m) <i>n</i> -Pentane	NMT 300 ppm	
10. Heavy metals:		
a) rhodium content	NMT 20 ppm	
b) chromium content	NMT 20 ppm	



CERTIFICATE OF QUALITY

No.:

page 3 of 3

TEST METHOD:	SPECIFICATION:	RESULT:
11. Microbial testing (CFU/g)		
Total aerobic microbial count	NMT 10^2 (2×10^2) CFU/g	
Total yeasts & moulds count	NMT 10^1 (2×10^1) CFU/g	
Specific microorganisms:		
- Bile-tolerant G ⁻ bacteria	0 CFU/g	
- Salmonella sp.	0 CFU/g	
- Escherichia coli	0 CFU/g	
- Staphylococcus aureus	0 CFU/g	
- Pseudomonas aeruginosa	0 CFU/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 SBR0380K/04, App. No. 1

Note: product conforms to the specification in USP 36 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: