

CERTIFICATE OF QUALITY

No.: 2307B061

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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.: 2306S001

PRODUCTION DATE: 06/2023

ATEST No.: A230133

RE-TEST DATE: 06/2026

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) by IR spectrum	IR spectrum conforms with IR of RS USP	IR spectrum conforms
b) by RT WS HPLC	RT of WS HPLC	RT conforms
2. Appearance		
a) visual evaluation	a white to off white crystalline material	a white crystalline material
b) spectrophotometric evaluation	the sum of absorbance NMT 0.150	0.004
3. Assay (HPLC, calculated with reference to anhydrous substance, abs. %):		
	96.0 - 102.5 % *	99.1 %
4. HPLC purity (USP HPLC method):		
Test 1		
a) PGA ₁ (abs. %)	NMT 1.3 %	0.0 %
b) PGB ₁ (abs. %)	NMT 0.1 %	not detected
c) impurity with RRT 0.6 (PGA ₁) (norm %)	NMT 0.9 %	not detected
d) other impurities single (norm %)	NMT 0.9 %	0.1 %
Test 2		
e) Σ impurities with RRT 2.0 and 2.3 (PGE ₁) (norm. %)	NMT 0.6 %	not detected
f) other impurities single (norm. %)	NMT 0.9 %	0.1 %
g) impurities total (Test 1 and Test 2) (norm %)	NMT 2.0 %	0.2 %

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TEST METHOD:	SPECIFICATION:	RESULT:
5. HPLC purity (in-house HPLC method, mol. %):		
a) 14-methyl-PGE ₁	NMT 0.5 %	not detected
b) 15R-PGE ₁	NMT 0.1 %	not detected
c) 4-trans-PGE ₂	NMT 0.5 %	not detected
d) 5-trans-PGE ₂	NMT 0.5 %	not detected
e) 6-trans-PGE ₂	NMT 0.5 %	0.0 %
f) PGD ₁	NMT 0.1 %	0.0 %
g) 13,14-dihydro-PGE ₁	NMT 0.5 %	not detected
h) other impurities single	NMT 0.1 %	0.1 %
i) other impurities total	NMT 2.0 %	0.1 %
6. Water content	NMT 0.5 %	0.1 %
7. Residue on ignition	NMT 0.5 %	0.0 %
8. Spec. optic rotation (c=0.5, ethanol) [α] _D ²⁰	-70.0° to -60.0°	- 68.8°
9. Content of solvents (USP GC method):		
a) Acetone	NMT 0.5 %	< 0.5 %
b) Chloroform	NMT 10 ppm	not detected
c) <i>n</i> -Hexane	NMT 290 ppm	not detected
d) Dichloromethane	NMT 5 ppm	not detected
e) Tetrahydrofuran	NMT 10 ppm	not detected
f) Ethyl acetate	NMT 300 ppm	not detected
g) <i>tert.</i> 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) <i>n</i> -Heptane	NMT 300 ppm	not detected
k) Toluene	NMT 20 ppm	not detected
l) <i>n</i> -Pentane	NMT 300 ppm	< 300 ppm
10. Heavy metals:		
a) rhodium content	NMT 20 ppm	14 ppm
b) chromium content	NMT 20 ppm	< 1 ppm

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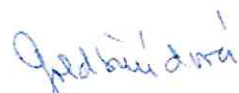
TEST METHOD:	SPECIFICATION:	RESULT:
11. Microbial testing (CFU/g)		
Total aerobic microbial count	NMT 10^2 (2×10^2) CFU/g	< 100 CFU/g
Total yeasts & moulds count	NMT 10^1 (2×10^1) CFU/g	< 10 CFU/g
Specific microorganisms:		
- Bile-tolerant G ⁻ bacteria	0 CFU/g	not found
- Salmonella sp.	0 CFU/g	not found
- 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 valid version SBR380K, App. No. 1

Note: product conforms to the specification in USP 44 and Microbial testing of product conforms to the specification in Ph.Eur. 11, harmonised method



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



Date: July 20, 2023