

CERTIFICATE OF QUALITY

No.: 2105B032

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

BATCH No.: 2104V001

PRODUCTION DATE: 04/2021

ATEST No.: A210096

RETEST DATE: 04/2024

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	RT of WS HPLC	RT conforms
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 % *	100.3 %
4. HPLC purity (Ph.Eur. HPLC method, norm. %):		
a) PGA ₁	NMT 1.3 %	not detected
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
j) PGE ₁ isopropylester	NMT 0.3 %	not detected
k) TPPO	NMT 0.5 %	not detected
l) unspecified impurities single	NMT 0.10 %	0,06 %
m) impurities total	NMT 1.5 %	0.1 %

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TEST METHOD:	SPECIFICATION:	RESULT:
12. Microbial testing (CFU/g):		
Total aerobic microbial count	NMT 10^2 (2×10^2) CFU/g	<10 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 SBR380K/08, 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.



Dagmar Goldšmídová

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

Date: May 21, 2021