

CERTIFICATE OF QUALITY

No.: 1311D313

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CUSTOMER: A.C.E.F. S.p.A.

PRODUCT: **ALPROSTADIL**
7-((1R,2R,3R*)-3-Hydroxy-2-[(E-(3S)-3-hydroxy-1-octenyl]-5-oxocyclopentyl)-heptanoic acid
C₂₉H₃₄O₅ = 354.5
CAS – 745-65-3

BATCH No.: 1303V01

PRODUCTION DATE: 03/2013

ATEST No.: A130065

QUANTITY: 1.0 g

RE-TEST DATE: 03/2016

TEST METHOD:	SPECIFICATION:	RESULT:
1. Identification		
a) by IR spectrum	IR spectrum of CRS Ph.Eur.	IR spectrum conforms
b) by RT WS HPLC	RT of WS HPLC	RT conforms
2. Description		
a) visual	a white or off white crystalline material	a white crystalline material
b) by absorbance	the sum of absorbance NMT 0.150	0.007
3. Assay (HPLC, calculated with reference to anhydrous substance, abs. %):		
	96.0 - 102.5 % *	99.7 %
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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TEST METHOD:	SPECIFICATION:	RESULT:
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 %
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 %	0.04 %
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 %	not detected
6. Water content	NMT 0.5 %	< 0.1 %
7. Residue on ignition	NMT 0.5 %	0.1 %
8. Spec. optic rotation (c=1, ethanol) [α] _D ²⁰	-70.0° to -60.0°	- 68.1°
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) <i>tert.</i> Butyl alcohol	NMT 300 ppm	not detected
j) Isopropyl alcohol	NMT 300 ppm	not detected
k) <i>n</i> -Heptane	NMT 300 ppm	not detected
l) Toluene	NMT 20 ppm	not detected
m) <i>n</i> -Pentane	NMT 300 ppm	< 300 ppm

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TEST METHOD:	SPECIFICATION:	RESULT:
11. Heavy metals:		
a) rhodium content	NMT 20 ppm	8 ppm
b) chromium content	NMT 20 ppm	1 ppm
12. 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 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.

Dagmar Goldšmídová

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



Date: Nov 22, 2013