

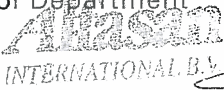

CERTIFICATE OF ANALYSIS

product	ALFAGLANDIN C, solution for injection	date of manufacture	12.2017
code	074	batch number	1712374.01
		date of expiry	12.2020

specifications	results	requirements
Appearance	conform	clear, almost colourless watery solution
Density	1.010	0.995 - 1.015 g/ml
Acidity	5.6	5.3 – 6.3 pH units
Active ingredients:		
- Identification Cloprostenol sodium	positive	positive
- Quantitative analysis Cloprostenol	0.2468	0.2375 – 0.2625 mg/ml
Purity tests:		
-Individual impurities	0.5	≤ 0.7% of the area of the main cloprostenol peak
-Total impurities	0.8	≤ 1.0% of the area of the main cloprostenol peak
Preservatives:		
-Chlorocresol	1.01	0.95 – 1.05 mg/ml
Sterility	sterile	sterile
Container	conform	injection vials, 20 ml
Closures	conform	bromobutylrubber stoppers and non re-usable aluminum closures

remarks

We hereby certify that the above mentioned information is authentic and accurate. This batch of product has been manufactured, including packaging / labeling and quality control in full compliance with the GMP-requirements of the local regulatory authority and with the specifications as agreed with the marketing authorization holder/contract giver of the importing country. The batch processing, packaging and analyses records were reviewed and found to be in compliance with GMP. The batch is released for the market.

date of report	Quality Control Department
28-12-2017	 Woerden:  Ir. A.P.F. Philipsen Qualified Person
	P.O. Box 78 3440 AB Woerden Holland