



Certificate of Analysis

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Puurs Batch Number: B03443
Product Name: DINOLYTIC SS 5MG/ML 5X10ML V
(DINOPROST TROMETHAMINE)
Material Number: 3032728028
Date of Manufacture: 03-2014
Expiration Date: 02-2016

Date Generated: 06-2014

Specification Name: P0327004001EU

TEST	RESULT	UNIT	LIMITS
BENZYL ALCOHOL	16.0	MG/ML	14.0 TO 18.2 MG/ML
CLARITY	MEETS TEST		NMT REFERENCE II
COLOR	MEETS TEST		NMT BY 5
DESCRIPTION	MEETS TEST		COLORLESS SOLUTION
DINOPROST	4.99	MG/ML	4.75 TO 5.25 MG/ML AT TIME OF RELEASE, 4.50 TO 5.25 MG/ML DURING SHELF LIFE
ENDOTOXINS	MEETS TEST		NMT 5 EU/0.6 MG DINOPROST
EXTRACTABLE VOLUME	MEETS TEST		MEETS PH EUR REQUIREMENTS
IDENTIFICATION BENZYL ALCOHOL	POSITIVE		POSITIVE
IDENTIFICATION DINOPROST	POSITIVE		POSITIVE
PARTICLES >= 10 MCM	61	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
PARTICLES >= 25 MCM	1	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
PH	6.8		6.0 TO 7.0
STERILITY	MEETS TEST		MEETS PH EUR REQUIREMENTS
IMPURITIES TOTAL	0.7	% OF LABEL >	NMT 8.5 % OF LABEL
15-R EPIMER	< 0.1	% OF LABEL	NMT 4.5 % OF LABEL

BATCH: B01427

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.
THIS BATCH OF PRODUCT HAS BEEN FABRICATED/MANUFACTURED, INCLUDING PACKAGING AND QUALITY
CONTROL IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY
AND WITH THE SPECIFICATIONS IN THE MARKETING AUTHORISATION OF THE IMPORTING COUNTRY:

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THE BATCH PROCESSING/PACKAGING AND ANALYSIS WERE
REVIEWED AND FOUND TO BE IN COMPLIANCE WITH GMP.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: Ilse De Keuster Lot Release Local Timestamp: 06-JUN-2014 11:56:42 Server Timestamp:
06-JUN-2014 11:56:36

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Diszpó: PN-ZA14001068 Vevő: Alpha-Vet 8000 File név: PN00008038 Egyedi sorszám: PN0000073041 1 másola
Szállító: Zoetis Hungary Kft. Oldal/Lap 1 / 1 Anyaglap: PN0283/14
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2014.11.13

CertEx v 3.03