



Certificate of Analysis

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Puurs Lot Number: A09453

Date Generated: 12-2013

Product Name: DINOLYTIC SS 5MG/ML 5X10ML V
(DINOPROST TROMETHAMINE)

Item Number: 3032728028

Date of Manufacture: 08-2013

Expiration Date: 07-2015

Specification Name: P0327004001EU

TEST	RESULT	UNIT	LIMITS
BENZYL ALCOHOL	16.5	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	5.01	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	82	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
PARTICLES >= 25 MCM	1	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
PH	6.5		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: A06650

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:

HUNGARY - HU

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: Karel De Schrijver Lot Release Local Timestamp: 13-DEC-2013 10:37:25 Server Timestamp:
13-DEC-2013 10:37:14

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Diszpó: PN-ZA14000160 Vevő: TolnAgro Kft 7100 File név: PN00007726 Egyedi sorszám: PN000007064 4 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 1 / 1 Anyaglap: PN0025/14
Az eredetivel megegyező elektronikus másolat a(z):
Dr. Nagy Edith min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2014.02.20 CertEx v 3.02