

## CERTIFICATE OF ANALYSIS



Generated Date:  
Jun 2, 2018

ZOETIS BELGIUM SA, a wholly-owned subsidiary of Zoetis Inc.  
RUE LAID BURNIAT, 1  
B-1348 LOUVAIN-LA-NEUVE  
BELGIUM  
AUTHORIZATION NUMBER 419V

Item: 10002890  
Title: DINOLYTIC 5X10ML  
Expiration Date: 02/2020  
Date Of Manufacture: 26/02/2018  
Market: Hungary-Croatia-Serbia-Slovenia  
Lot Number: 289343 Associated Lots: 283987

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Description	Clear and colourless solution, practically free from visible particles.	N/A	Conform
Clarity	Not more than Reference II	N/A	Conform
Color	Not more than BY 5	N/A	Conform
pH	6.0 - 7.0	N/A	6.4
Extractable volume	Actual volume >= Nominal volume	N/A	Conform
Benzyl Alcohol identification	Positive for benzyl alcohol	N/A	Positive
Benzyl Alcohol content	14.9 - 18.2	mg/mL	17.5
Dinoprost identification	Positive for Dinoprost	N/A	Positive
Dinoprost content	4.75 - 5.25	mg/mL	5.11
Single unidentified impurities content	<= 1.0	%	Not detected
Total impurities content	<= 3.0	%	0.6
15-R Epimer percent content	<= 1.2	%	Not detected
Particulate contamination	<= 6000 particles >= 10µm/vial	N/A	71

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<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Particulate contamination	<= 600 particles >= 25µm/vial	N/A	20
Sterility	No growth	N/A	No Growth
Endotoxin content	<= 42 (equivalent to ≤ 5 EU/0.6mg dinoprost)	EU/mL	< 10

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Lot Release Electronic Signature: Philippe Perz  
Lot Release System Timestamp: May 30, 2018 7:10:04 AM

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Diszpó: PN0803891405 Vev: Szabolcs-Sz-B m-i File név: PN00009657 Egyedi sorszám: PN000008755 9 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0234/18  
Az eredetivel megegyez elektronikus másolat a(z):  
Dr. Jakab Mihály min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2018.07.11 CertEx v 3.03a