

CERTIFICATE OF ANALYSIS



Generated Date:
Sep 16, 2019

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: 02/2021
Date Of Manufacture: 19/03/2019
Market: Hungary-Croatia-Serbia-Slovenia
Lot Number: 385304 Associated Lots: 358807

<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	6.3
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	16.6
Dinoprost identification	Positive for Dinoprost	N/A	Positive
Dinoprost content	4.75 - 5.25	mg/mL	5.02
Single unidentified impurities content	<= 1.0	%	Not detected
Total impurities content	<= 3.0	%	0.7
15-R Epimer percent content	<= 1.2	%	Not detected
Particulate contamination	<= 6000 particles >= 10µm/vial	N/A	317

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

CERTIFICATE OF ANALYSIS



Generated Date:
Sep 16, 2019

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: 02/2021
Date Of Manufacture: 19/03/2019
Market: Hungary-Croatia-Serbia-Slovenia
Lot Number: 385304 Associated Lots: 358807

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Particulate contamination	<= 600 particles >= 25µm/vial	N/A	5
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: Sep 16, 2019 6:48:06 AM

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Diszpó: PN0807491421 Vevő: DR SZEKELY KFT Erd File név: PN00010237 Egyedi sorszám: PN0000092044 1 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0393/19
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2019.10.26
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v 3.10