

Generated Date:
Feb 14, 2020

CERTIFICATE OF ANALYSIS

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: 08/2021
 Date Of Manufacture: 25/09/2019
 Market: Hungary-Croatia-Serbia-Slovenia
 Lot Number: 414580 Associated Lots: 386165

<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 \geq 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	5.10
Single unidentified impurities content	\leq 1.0	%	Not Detected
Total impurities content	\leq 3.0	%	0.8
15-R Epimer percent content	\leq 1.2	%	0.1
Particulate contamination	\leq 6000 particles \geq 10 μ m/vial	N/A	405

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Particulate contamination	<= 600 particles >= 25µm/vial	N/A	7
Sterility	No growth	N/A	No Growth
Endotoxin content	<= 42 (equivalent to ≤ 5 EU/0.8mg 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.

Batch Release Authorized by Electronic Signature: Sophie le Grelle
Position/Title: Qualified Person
Lot Release System Timestamp: Feb 14, 2020 9:07:24 AM UTC

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Diszpó: PN0808605089 Vevő: DR SZEKELY KFT Erd File név: PN00010406 Egyedi sorszám: PN0000093789 3 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0081/20
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2020.03.20
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10