

## **CERTIFICATE OF ANALYSIS**

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FINISHED PRODUCT

Product name:

CIMALGEX 80MG 144 UA

444119

Manufacturing date:

01/04/2021

Batch number:

1C1293C

Pharmaceutical form: Not Coated Tablets

Expiration date:

Analytical code:

31/03/2024

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	21.5 x 8.5 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence of three breaking lines on both sides	Pass
Average mass and tablet mass variation		
Average mass	>=1045 <= 1155 mg	1107 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Quarter-tablet content uniformity	<= 15.0 (Eur. Ph.2.9.40)	3.9
Cimicoxib dissolution  Average Dissolution	>= 75 % in 45 min	101 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC) Cimicoxib content	>= 76.0 <= 84.0 mg/tab	79.3 mg/tab.
Cimicoxib impurities (HPLC)		
Each unknown impurity	<= 0.3 % area	<0.1 % area
Total unknown impurities	<= 1.0 % area	<0.1 % area

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in the current European Union rules for Good Manufacturing Practice for medicinal products for veterinary use, and that the finished product in all aspects answers the requirements laid down in the marketing authorisation.

Released by Qualified Person:

Brian LOYON

Date:

29/07/2021 16:43:54

Decision:

**FULL RELEASE** 

This document has been produced electronically and is valid without a signature.

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE