

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT			
Product name :	CIMALGEX 30MG 144 UA	Analytical code :	444118
Pharmaceutical form :	Not Coated Tablets	Manufacturing date :	30/04/2021
Batch number :	1C1639E	Expiration date :	29/04/2024

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	15 x 6.5 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence of two breaking lines on both sides	Pass
Average mass and tablet mass variation		
Average mass	$\geq 392 \leq 433$ mg	417 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Third-tablet content uniformity	≤ 15.0 (Eur. Ph 2.9.40)	10.3
Cimicoxib dissolution		
Average Dissolution	≥ 75 % in 45 min	102.167 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	$\geq 28.5 \leq 31.5$ mg/tab	29.9 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 :	Adriana TASSI
Date :	19/11/2021 16:31:51
Decision :	FULL RELEASE

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

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