


vetoquinol
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CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : CIMALGEX 80MG 32 HR HU RO **Analytical code :** 443241
Pharmaceutical form : Not Coated Tablets **Manufacturing date :** 10/02/2020
Batch number : 0C0432J **Expiration date :** 09/02/2023

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	$\geq 1045 \leq 1155$ 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)	3.6
Cimicoxib dissolution		
Average Dissolution	≥ 75 % in 45 min	100.333 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	$\geq 76.0 \leq 84.0$ mg/tab	79.4 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 : 17/09/2020 07:35:24
Decision : FULL RELEASE

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

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

Magny-Vernois I.B.P. 189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOGUINCL S.A. au Capital de 29.764.755 € SIRET 676 250 111 00017 RCS VESUL GRAY B 676 250 111