

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 :	14/02/2018
Batch number : 8C0527E	Expiration date :	13/02/2021
TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	
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	1106 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Quarter-tablet content uniformity	<= 15.0 (Eur. Ph.2.9.40)	5.8
Cimicoxib dissolution		
Average Dissolution	>= 75 % in 45 min	102.833 %
Cimicoxib identity (HPLC)		Pass
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	>= 76.0 <= 84.0 mg/tab	79.7 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 : 15/06/2018 16:55:11
Decision : FULL RELEASE

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

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VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 000171 | RCS VESOUL GRAY B 676 250 111

PHOENIX Pharma Zrt.
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..... sz. másolati példány
Csak a piros szín hiteles!
Min. biz.