

**vetoquinol**
ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT		
Product name :	CLAVASEPTIN 50 10 CY HU RO	Analytical code : 426052
Pharmaceutical form :	Not Coated Tablets	Manufacturing date : 31/08/2018 /
Batch number :	8C2590V /	Expiration date : 30/08/2020 /
TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	$\geq 9.8 \leq 10.2$ mm	10.1 mm
Average weight and uniformity of weight		
Average mass	$\geq 90.4 \leq 100.0$ mg	95.7 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	≥ 30 N	38 N
Disintegration test	≤ 15 min	<4 min
Equilibrium relative humidity	≤ 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	97 %
Amoxicillin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	100 %
Clavulanic ac dissolution compliance	Complies with EP 2.9.3.	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin UV spectrum	Positive	Pass
Amoxicillin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicillin content	$\geq 38.00 \leq 42.00$ mg/tablet	39.25 mg/tab.
Clavulanic acid content	$\geq 9.78 \leq 10.82$ mg/tablet	9.99 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VÉTÉRIINAIRE

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
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

PHOENIX Pharma Ltd.
Fóti Telephely
2151 Fót, Keleti Márton út 19.
..... sz. másolati példány
Csak a piros szín hiteles!
20-03



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Pharmaceutical form :	Not Coated Tablets	Manufacturing date : 31/08/2018
Batch number :	8C2590V	Expiration date : 30/08/2020
TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	<0.3 % w/w
Imp.B	<= 1.0 %w/w	<0.3 % w/w
Imp.C	<= 1.0 %w/w	<0.3 % w/w
Imp.D	<= 1.0 %w/w	<0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.3 % w/w
Imp.F	<= 1.0 %w/w	<0.3 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	0.4 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.3 % w/w
Total unidentified degradation products	<= 2.0 %w/w	<0.3 % w/w
Total degradation products	<= 3.0 %w/w	0.9 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	<0.3 % area
Total degradation products	<= 2.0 %area	<0.3 % 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 :	Paul-Adrien MATHON
Date :	20/11/2018 10:06:36
Decision :	FULL RELEASE

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Magny-Vernois | B.P. 189 | 70204 Lure Cedex | France | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 000171 | RCS VESOUL GRAY B 676 250 111

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