

vetoquinol
 ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

Page 1/2

FINISHED PRODUCT		
TESTS	SPECIFICATIONS	RESULTS
Product name :	CLAVASEPTIN 250 10 CY HU RO	Analytical code : 426055
Pharmaceutical form :	Not Coated Tablets	Manufacturing date : 12/02/2018
Batch number :	8C0468F	Expiration date : 11/02/2021
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 16.8 <= 17.2 mm	17.2 mm
Average weight and uniformity of weight		
Average mass	>= 452.2 <= 499.8 mg	477.3 mg
Uniformity of mass	Complies with EP 2.9.5.	Pass
Resistance to crushing	>= 60 N	110 N
Disintegration test	<= 15 min	<6 min
Equilibrium relative humidity	<= 15 %	9 %
Amoxicillin dissolution rate	Q=85% within 30 min	101 %
Amoxicillin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	102 %
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	>= 190 <= 210 mg/tablet	196 mg/tab.
Clavulanic acid content	>= 48.9 <= 54.1 mg/tablet	51.1 mg/tab.

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

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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

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



ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

Page 2/2

FINISHED PRODUCT			
Product name :	CLAVASEPTIN 250 10 CY HU RO	Analytical code :	426055
Pharmaceutical form :	Not Coated Tablets	Manufacturing date :	12/02/2018
Batch number :	8C0468F	Expiration date :	11/02/2021

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	0.4 % w/w
Imp.K	<= 1.0 %w/w	0.5 % 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	<0.3 % 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 :	Brian LOYON
Date :	28/05/2018 17:38:23
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
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

PHOENIX Pharma Zrt.
Fóti Telephely
2151 Fóti, Keleti Márton út 19.
..... sz. másolati példány
Csak a Mins biz. hiteles!
20-03

Meoszám:180700031/07/T

6.pld. Kiadva: 18/10/04