

  
**vetoquinol**  
ACHIEVE MORE TOGETHER  
**CERTIFICATE OF ANALYSIS**

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FINISHED PRODUCT		
Product name : CLAVASEPTIN 250 10 CY HU RO	Analytical code : 426055	
Pharmaceutical form : Not Coated Tablets	Manufacturing date : 06/09/2019	
Batch number : 9C2522C	Expiration date : 05/09/2022	
TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	$\geq 16.8 \leq 17.2$ mm	17.1 mm
Average weight and uniformity of weight		
Average mass	$\geq 452.2 \leq 499.8$ mg	478.9 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	$\geq 60$ N	102 N
Disintegration test	$\leq 15$ min	<5 min
Equilibrium relative humidity	$\leq 15$ %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	103 %
Amoxicillin dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	107 %
Clavulanic ac dissolution compliance	Complies with Eur. Ph. 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	$\geq 190 \leq 210$ mg/tab	203 mg/tab.
Clavulanic acid content	$\geq 48.0 \leq 54.1$ mg/tab	50.3 mg/tab.

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**LABORATOIRE PHARMACEUTIQUE VÉTÉRIKAIRE**

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VETUQUINOL S.A. au capital de 29 704 765 € | SIRET 476 250 111 0001 | RCS VESOUL GRAY B 676 250 111

Meoszám:191200013MBT

6.pld. Kiadva: 20/09/14

**MEDIMPEX GYÓGYSZER ZRT.**  
1158 Bp., Rákospalotai határút 2.  
Nagyné Kári Min. biz. :  
Minőségbiztosító szakasszisztens  
Csak a piros színű hiteles

  
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Batch number : 9C2522C	Expiration date : 05/09/2022	
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	0.4 % 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	1.3 % 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 :	Paul-Adrien MATHON
Date :	30/10/2019 16:53:38
Decision :	FULL RELEASE

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VETOQUINOL S.A. au Capital de 29 704 755 € | SIRET : 476 250 111 000121 | RCS VESGUL GRAY R 676 250 111

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MEDIMPEX GYÓGYSZER ZRT.  
1158 Bp. Rákospalotai határút 2.  
Nagyéka út 2.  
Minőségbiztosító szakasszisztens  
Csak a piros szín hiteles