

**vetoquinol**  
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**CERTIFICATE OF ANALYSIS**

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FINISHED PRODUCT		
TESTS	SPECIFICATIONS	RESULTS
Product name :	CLAVASEPTIN 50 10 CY HU RO	Analytical code : 426052
Pharmaceutical form :	Not Coated Tablets	Manufacturing date : 05/06/2018 ✓
Batch number :	8C1803P ✓	Expiration date : 04/06/2020 ✓
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	95.2 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	$\geq 30$ N	41 N
Disintegration test	$\leq 15$ min	<4 min
Equilibrium relative humidity	$\leq 15$ %	14 %
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	$\geq 38.00 \leq 42.00$ mg/tablet	40.29 mg/tab.
Clavulanic acid content	$\geq 9.78 \leq 10.82$ mg/tablet	9.86 mg/tab.

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**LABORATOIRE PHARMACEUTIQUE VÉTÉRIINAIRE**

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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 Fót, Keleti M. u. 19.  
Csak a piros szín hiteles!  
20-03



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**FINISHED PRODUCT**

<b>Product name :</b>	CLAVASEPTIN 50 10 CY HU RO	<b>Analytical code :</b>	426052
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TESTS	SPECIFICATIONS	RESULTS
<b>Amoxicillin purity (HPLC)</b>		
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	0.5 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	<0.3 % 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	1.2 % w/w
<b>Clavulanic acid impurities (HPLC)</b>		
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.

<b>Released by Qualified Person :</b>	<b>Paul-Adrien MATHON</b>
<b>Date :</b>	22/10/2018 15:57:25
<b>Decision :</b>	FULL RELEASE

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Meoszám:181100298/07/T

5.pld. Kiadva: 19/01/10