

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

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**FINISHED PRODUCT**

<b>Product name :</b> CLAVASEPT 50MG CPR100 GR HU RO	<b>Analytical code :</b> 456277
<b>Pharmaceutical form :</b> Not Coated Tablets	<b>Manufacturing date :</b> 25/06/2019
<b>Batch number :</b> 9C1963J	<b>Expiration date :</b> 24/06/2021

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	96.2 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	$\geq 30$ N	49 N
Disintegration test	$\leq 15$ min	<4 min
Equilibrium relative humidity	$\leq 15$ %	13 %
Amoxicillin dissolution rate	Q=85% within 30 min	102 %
Amoxicillin dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	103 %
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	$\geq 38.00 \leq 42.00$ mg/tab	41.02 mg/tab.
Clavulanic acid content	$\geq 9.78 \leq 10.82$ mg/tab	9.82 mg/tab.

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**LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE**

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VETODUINOL S.A. au Capital de 29.704.755 € | SIRET 874 256 111 00017 | RCS VESOUL GRAY B 874 253 111

Meoszám:191100024MBT

4.pld. Kiadva: 19/11/27

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

  
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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	0.6 % 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 :

Date :

Decision :

Brian LOYON

16/10/2019 17:24:34

FULL RELEASE

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