

**vetoquinol**
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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 :** 31/01/2019
Batch number : 9C0360K **Expiration date :** 30/01/2021

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	95.9 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	≥ 30 N	46 N
Disintegration test	≤ 15 min	< 4 min
Equilibrium relative humidity	≤ 15 %	9 %
Amoxicillin dissolution rate	Q=85% within 30 min	98 %
Amoxicillin dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	99 %
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	40.64 mg/tab.
Clavulanic acid content	$\geq 9.78 \leq 10.82$ mg/tab	9.87 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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VETOQUINOL S.A. au Capital de 29.204.755 € SIRET 676 250 111 00017 RCS VESOUL GRAY B 676 250 111

Meoszám:190600061MBT

6.pld. Kiadva: 19/07/19

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp. Rákospalotai határút 2.
Nagyencsán D-2
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles

CLAVASEPTIN 50MG ÍZES.TBL.KUTYAMACSKA
Gysz:9C0360K Lej:21/01/30
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
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FINISHED PRODUCT	
Product name :	CLAVASEPTIN 50 10 CY HU RO
Analytical code :	426052
Pharmaceutical form :	Not Coated Tablets
Manufacturing date :	31/01/2019
Batch number :	9C0360K
Expiration date :	30/01/2021

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	0.4 % w/w
Imp.G	<= 1.0 %w/w	<0.3 % 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	0.4 % 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
27/05/2019 18:16:46
FULL RELEASE

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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VETOQUINOL S.A. au Capital de 29 704 755 € SIRET 692 250 111 000171 RCS VESOUL GRAY B 676 250 111

Meoszám:190600061MBT

6.pld. Kiadva: 19/07/19

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Nagyné Kári Éva
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