CLAVASEPTIN 250MG ÍZESTABL.KUTYA&MACSKA
Gysz:9C0039G Lej:22/01/06
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel:+36-1-414-6477
Fax:+36-1-414-6479

vetoquinol
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250 10 CY HU RO	**Analytical code :**	426055
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	07/01/2019
Batch number :	9C0039G	**Expiration date :**	06/01/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 16.8 <= 17.2 mm	17.1 mm
Average weight and uniformity of weight		
Average mass	>= 452.2 <= 499.8 mg	478.7 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	>= 60 N	94 N
Disintegration test	<= 15 min	<4 min
Equilibrium relative humidity	<= 15 %	9 %
Amoxicillin dissolution rate	Q=85% within 30 min	101 %
Amoxicilin 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)		
Amoxicilin UV spectrum	Positive	Pass
Amoxicilin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicilin content	>= 190 <= 210 mg/tab	201 mg/tab.
Clavulanic acid content	>= 48.9 <= 54.1 mg/tab	51.3 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE
Magny-Vernois : B.P.189 : 70204 Lure Cedex (France) : TEL. : +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

Meoszám:190500020MBT 5.pld. Kiadva: 19/06/13

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
Nagyné Kári Éva
Minőségügyi 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	<0.3 % w/w
Imp.F	<= 1.0 %w/w	0.4 % 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	0.9 % 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
Half-tablets weight unif. (1/yr)	Complies with Eur. Ph. 2.9.5	Pass
Microbiological quality		
TAMC (once a year)	<= 1000 cfu/g	<100 cfu/g
TYMC (once a year)	<= 100 cfu/g	<100 cfu/g
Escherichia coli (once a year)	Absence in 1 g	Absence

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 :	12/04/2019 07:39:26
Decision :	FULL RELEASE

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