CLAVASEPTIN 500MG ÍZESTBL.KUTYA&MACSKA
Gysz:9C0390C Lej:22/02/03
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
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vetoquinol
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 500 10 CY HU RO	**Analytical code :**	426057
		Manufacturing date :	04/02/2019
Pharmaceutical form :	Not Coated Tablets		
Batch number :	9C0390C	**Expiration date :**	03/02/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 20.8 <= 21.2 mm	21.2 mm
Average weight and uniformity of weight		
Average mass	>= 904.4 <= 999.6 mg	960.5 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	>= 80 N	125 N
Disintegration test	<= 15 min	<6 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	104 %
Clavulanic ac dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin 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		
Amoxicillin content	>= 380 <= 420 mg/tab	409 mg/tab.
Clavulanic acid content	>= 97.8 <= 108.2 mg/tab	104.6 mg/tab.

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Meoszám:190600062MBT 8.pld. Kiadva: 19/09/16

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

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FINISHED PRODUCT

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Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	04/02/2019
Batch number :	9C0390C	**Expiration date :**	03/02/2022

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	0.4 % 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	0.7 % 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 :	21/05/2019 07:49:14
Decision :	FULL RELEASE

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Meoszám:190600062MBT 8.pld. Kiadva: 19/09/16 Min.biz.:

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