CLAVASEPTIN 500MG ÍZESTBL.KUTYA&MACSKA
Gysz:9C1521E Lej:22/05/19
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
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vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : CLAVASEPTIN 500 10 CY HU RO
Analytical code : 426057
Manufacturing date : 20/05/2019
Pharmaceutical form : Not Coated Tablets
Expiration date : 19/05/2022
Batch number : 9C1521E

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 20.8 <= 21.2 mm	21.1 mm
Average weight and uniformity of weight		
Average mass	>= 904.4 <= 999.6 mg	959.3 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	>= 80 N	132 N
Disintegration test	<= 15 min	<5 min
Equilibrium relative humidity	<= 15 %	12 %
Amoxicillin dissolution rate	Q=85% within 30 min	103 %
Amoxicilin dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	106 %
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	>= 380 <= 420 mg/tab	407 mg/tab.
Clavulanic acid content	>= 97.8 <= 108.2 mg/tab	103.5 mg/tab.

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VETOQUINOL S.A. au Capital de 29.764.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

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1158 Bp., Rákospalotai határút 2.
HEGEDÜS KLAUDETTA
Minőségbiztosítási Vezető
Csak a piros szín hiteles

Meoszám:191100023MBT 7.pld. Kiadva: 20/07/27

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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	0.6 % 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	1.0 % 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 : Brian LOYON
Date : 09/10/2019 17:58:59
Decision : FULL RELEASE

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