

CLAVASEPTIN 250MG ÍZESTABL.KUTYA&MACSKA
Gysz:8C1794G Lej:21/06/03
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
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Clavaseptin 250mg ízesített tablett
Gysz:8C1794G Lej:21/06/03
Kisz:10x Me.:darab
MEDIMPEX GYÓGYSZER ZRT. részére

2151 Fót
Keleti Márton u. 19.
Tel:27/537-100
Fax:27/537-100


vetoquinol
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CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT			
Product name :	CLAVASEPTIN 250 10 CY HU RO	Analytical code :	426055
Pharmaceutical form :	Not Coated Tablets	Manufacturing date :	04/06/2018
Batch number :	8C1794G	Expiration date :	03/06/2021
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 <= 469.8 mg	477.7 mg	
Uniformity of mass	Complies with EP 2.9.5.	Pass	
Resistance to crushing	>= 80 N	101 N	
Disintegration test	<= 15 min	<4 min	
Equilibrium relative humidity	<= 15 %	11 %	
Amoxicillin dissolution rate	Q=65% within 30 min	100 %	
Amoxicillin dissolution compliance	Complies with EP 2.9.3.	Pass	
Clavulanic ac dissolution rate	Q=80% within 30 min	102 %	
Clavulanic ac dissolution compliance	Complies with EP 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	>= 190 <= 210 mg/tablet	200 mg/tab.	
Clavulanic acid content	>= 48.9 <= 54.1 mg/tablet	51.7 mg/tab.	

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LABORATOIRE PHARMACEUTIQUE VÉTÉRIINAIRE

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VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 000171 RCS VESOUL GRAY B 676 250 111

PHOENIX Pharma Zrt.
Fóti Telephely
2151 Fót, Keleti Márton út 19.
..... sz. másolatú példány
Csak a piros szín hiteles!
2019

Meoszám:190400041MBT

2.pld. Kiadva: 19/04/11

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
Nagyéné Kári Éva
Minőségirányítási Osztály
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Handwritten signature

CLAVASEPTIN 250MG ÍZESTABL.KUTYA&MACSKA
Gysz:8C1794G Lej:21/06/03
Kisz:10X Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
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Tel:+36-1-414-6477
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FINISHED PRODUCT

Product name : CLAVASEPTIN 250 10 CY HU RO	Analytical code : 428055
Pharmaceutical form : Not Coated Tablets	Manufacturing date : 04/06/2018
Batch number : 8C1794G	Expiration date : 03/06/2021

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	0.5 % 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
Clevulanic 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 :	Paul-Adrien MATHON
Date :	02/10/2018 19:07:24
Decision :	FULL RELEASE

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VETEOQUINOL S.A. au Capital de 29.704.755 € | SIRET 674 250 111 00017 | RCS VESOUL GRAY B 674 250 111

Meoszám:181000653/07/T 7.pld. Kiadva: 19/03/29

Meoszám:190400041MBT 2.pld. Kiadva: 19/04/11

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotai határút 2.
Nagykanizsa
Minőségbiztosító szakasszisztens!
Csak a piros szín hiteles!

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
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