vetoquinol
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 500 10 CY HU RO	**Analytical code :**	426057
		Manufacturing date :	20/09/2017
Pharmaceutical form :	Not Coated Tablets	**Expiration date :**	19/09/2020
Batch number :	7C2688D		

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	960.8 mg
Uniformity of mass	Complies with EP 2.9.5.	Pass
Resistance to crushing	>= 80 N	137 N
Disintegration test	<= 15 min	<6 min
Equilibrium relative humidity	<= 15 %	13 %
Amoxicillin dissolution rate	Q=85% within 30 min	101 %
Amoxicilin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	103 %
Clavulanic ac dissolution compliance	Complies with EP 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/tablet	405 mg/tab
Clavulanic acid content	>= 97.8 <= 108.2 mg/tablet	105.2 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VETERINAIRE

PHOENIX Pharma Zrt.
Fő telephely
2151 Fót, Kelet M. u. 19.
Csak a piros szín hiteles!
20-03

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FINISHED PRODUCT

Product name : CLAVASEPTIN 500 10 CY HU RO

Analytical code : 426057

Manufacturing date : 20/09/2017

Pharmaceutical form : Not Coated Tablets

Expiration date : 19/09/2020

Batch number : 7C2888D

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

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 :	Anne SANTIPERI
Date :	29/11/2017 18:50:58
Decision :	FULL RELEASE

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LABORATOIRE PHARMACEUTIQUE VETERINAIRE
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