


vetoquinol
ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : CLAVASEP 250MG CPR100 GR HU RO **Analytical code :** 456278
Pharmaceutical form : Not Coated Tablets **Manufacturing date :** 05/09/2019
Batch number : 9C2515E **Expiration date :** 04/09/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	$\geq 16.8 \leq 17.2$ mm	17.2 mm
Average weight and uniformity of weight		
Average mass	$\geq 452.2 \leq 499.8$ mg	483.0 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	≥ 60 N	105 N
Disintegration test	≤ 15 min	< 4 min
Equilibrium relative humidity	≤ 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	100 %
Amoxicillin dissolution compliance	Complies with Eur. Ph. 2.9.3	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	105 %
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	$\geq 190 \leq 210$ mg/tab	202 mg/tab.
Clavulanic acid content	$\geq 48.9 \leq 54.1$ mg/tab	51.4 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VÉTÉRAIRE

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VETOQUINOL S.A. au Capital de 29 704 755 € - SIRET 676 250 111 (0017) RCS VESOUL GRAY B 676 250 111

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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	0.4 % w/w
Imp.F	<= 1.0 %w/w	<0.3 % w/w
Imp.G	<= 1.0 %w/w	0.4 % w/w
Imp.K	<= 1.0 %w/w	0.5 % 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	1.3 % 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 : 29/10/2019 17:04:40
Decision : FULL RELEASE

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

Meoszám:191100025MBT

4.pld. Kiadva: 19/11/27

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