vetoquinol
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250MG 100 BE NL PL	**Analytical code :**	436775
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	10/05/2022
Batch number :	2C1844C	**Expiration date :**	09/05/2025

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 <= 499.8 mg	479.6 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5	Pass
Resistance to crushing	>= 60 N	110 N
Disintegration test	<= 15 min	<5 min
Equilibrium relative humidity	<= 15 %	11 %
Amoxicillin dissolution rate	Q=85% within 30 min	100 %
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
Amoxicilin 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/tab	198 mg/tab.
Clavulanic acid content	>= 48.9 <= 54.1 mg/tab	52.0 mg/tab.

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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	0.4 % 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	1.1 % 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 :	Jean-François MAILLOT
Date :	19/10/2022 17:23:18
Decision :	FULL RELEASE

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