Clavaseptin 250mg ízesített tablett
Gysz:6A0646L Lej:19/02/24
Kisz:10x Me.:darab
DR. SZÉKELY KFT. részére

2151 Fót
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250 10 CY HU RO	**Analytical code :**	428055
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	25/02/2016
Batch number :	6A0646L	**Expiration date :**	24/02/2019

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 16.8 <= 17.2 mm	17.2 mm
Average weight and uniformity of weight		
Average mass	>= 452.2 <= 499.8 mg	479.8 mg
Uniformity of mass	Complies with EP 2.9.5.	Pass
Resistance to crushing	>= 60 N	110 N
Disintegration test	<= 15 min	<6 min
Equilibrium relative humidity	<= 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	101 %
Amoxicillin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	104 %
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	205 mg/tab.
Clavulanic acid content	>= 48.9 <= 54.1 mg/tablet	50.2 mg/tab.

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250 10 CY HU RO	**Analytical code :**	426055
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	25/02/2016
Batch number :	6A0648L	**Expiration date :**	24/02/2019

TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	0.2 % w/w
Imp.B	<= 1.0 %w/w	<0.1 % w/w
Imp.C	<= 1.0 %w/w	0.1 % w/w
Imp.D	<= 1.0 %w/w	0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.1 % 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	<0.1 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.1 % w/w
Total unidentified degradation products	<= 2.0 %w/w	0.0 % w/w
Total degradation products	<= 3.0 %w/w	1.3 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	0.2 % area
Total degradation products	<= 2.0 %area	0.2 % 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 :	23/06/2016 17:13:57
Decision :	FULL RELEASE

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