

Certificate of analysis

Name of the product: Cardisure 10 mg

Product number	: 97301019	Packing	: 100 tabl
Batch number Dechra	: 963528	Destination	: CZ/SK/HU
Batch number Supplier	: 18D106	CoA version	: SC-LAB97301019.2.0
Manufacturing date	: 04-2018		
Expiry date	: 10-2020		

DETERMINATIONS	SPECIFICATIONS	RESULTS
APPEARANCE OF TABLETS	A light brown round tablet, quadrisect, diameter 20 mm	A light brown round tablet, quadrisect, diameter 20 mm
APPEARANCE PRIMARY PACKAGING	No deviations	No deviations
AVERAGE MASS (mg/tablet)	1710 – 1890	1808
UNIFORMITY OF DOSAGE UNITS	Complies to Ph. Eur 2.9.40	Complies to Ph. Eur 2.9.4
RESISTANCE TO CRUSHING (N)	100 – 140	135
FRIABILITY (%)	Max. 1	1
DISSOLUTION RATE (%)	Q=75% in 30 min.	96
MICROBIOLOGICAL QUALITY	Ph. Eur 5.1.4 (Non aqueous preparation for oral use)	*Not applied
IDENTIFICATION OF PIMOBENDAN	Positive	Positive
ASSAY OF PIMOBENDAN (mg/tablet)	9.50 – 10.50	9.87

* Not routinely tested, at least once a year

Conclusion : Conform specifications.

Qualified Person

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Stefan van Roosmalen


05 JUN 2018