

Certificate of Analysis

Name of the product	: Sedaxylan inj.		
Product number	: 91505212	Packaging	: 50 ml
Batch number	: 099543	Date of analysis	: 15-06-2017
Manufacturing date	: 05-2017	CoA version	: SC-LAB91505212.3.0
Expiry date	: 05-2020	Destination	: Hungary

DETERMINATIONS	SPECIFICATIONS	RESULTS
CHARACTERS	Clear colourless solution	Clear colourless solution
CLARITY	As water	As water
COLOUR	Not more intensely coloured than reference solution B9	Not more intensely coloured than reference solution B9
IDENTIFIACATION	Conform	Conform
pH	4.5 - 5.5	5.0
RELATIVE DENSITY	1.02 - 1.04	1.03
VOLUME (ml)	50.0 – 51.5	50.5
STERILITY	Passes the test	Passes the test
ASSAY		
Xylazine (mg/ml)	19.0 – 21.0	19.5
Methyl parahydroxybenzoaat (mg/ml)	0.90 – 1.10	0.97
Propyl parahydroxybenzoaat (mg/ml)	0.090 – 0.110	0.093

Stefan van Roosmalen


13 OKT 2017

Qualified Person

Conclusion : Conform specifications.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.