

# Certificate of Analysis



Animal Health

Name of the product : Sedaxylan inj.

Product number : 91505212  
Batch number : 078348  
Manufacturing date : 09-2015  
Expiry date : 09-2018

Packaging : 50 ml  
Date of analysis : 29-09-2015  
CoA version : SC-LAB91505212.3.0  
Destination : Hungary

## DETERMINATIONS

## SPECIFICATIONS

## RESULTS

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	50.4
STERILITY	Passes the test	Passes the test
ASSAY		
Xylazine (mg/ml)	19.0 – 21.0	19.6
Methyl parahydroxybenzoaat (mg/ml)	0.90 – 1.10	0.97
Propyl parahydroxybenzoaat (mg/ml)	0.090 – 0.110	0.096

### 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.

Jeroen Van den Brande

26 JAN 2016

Qualified Person



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