

Certificate of Analysis

Name of the product : Sedaxylan inj.

Product number : 91505212

Batch number : 102752

Manufacturing date : 01-2018

Expiry date : 01-2021

Packaging : 50 ml

Date of analysis : 24-01-2018

CoA version : SC-LAB91505212.3.0

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

IDENTIFICATION

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

20.0

Methyl parahydroxybenzoaat (mg/ml)

0.90 – 1.10

0.99

Propyl parahydroxybenzoaat (mg/ml)

0.090 – 0.110

0.097

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.

Els de Meijer

18 APR 2018

Qualified Person

eurolvet

Animal Health

Dechra