

# Certificate of Analysis

Name of the product : Rapidexon

Product number : 91731606

Batch number : 097855

Manufacturing date : 05-2017

Expiry date : 05-2019

Packaging : 100 ml

CoA version : SC-LAB91731606.3.0

Date of analysis : 13-06-2017

Destination : Hungary

## DETERMINATIONS

## SPECIFICATIONS

## RESULTS

### CHARACTERS

A clear, colourless solution practically free from particles

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### CLARITY OF SOLUTION

As water

As water

### COLOUR

Not more intensely coloured than reference solution B9

Not more intensely coloured than reference solution B9

### IDENTITY

Positive

Positive

### DENSITY (g/ml)

1.00 - 1.02

1.01

### pH

7.0 - 8.1

7.8

### VOLUME (ml)

Minimum 100.0

101.1

### STERILITY

Passes the test

Passes the test

### ASSAY (mg/ml)

Dexamethasone

1.90 - 2.10

1.97

Benzylalcohol

14.3 -15.8

15.1

Stefan van Roosmalen



31 AUG 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.