

Certificate of Analysis



Name of the product : Rapidexon

Product number : 91731606

Batch number : 072132

Manufacturing date : 07-2015

Expiry date : 07-2017

Packaging : 100 ml

CoA version : SC-LAB91731606.3.0

Date of analysis : 03-09-2015

Destination : Hungary

DETERMINATIONS

SPECIFICATIONS

RESULTS

CHARACTERS

A clear, colourless solution practically free from particles

A clear, colourless solution practically free from particles

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

7.6

VOLUME (ml)

Minimum 100.0

100.8

STERILITY

Passes the test

Passes the test

ASSAY (mg/ml)

Dexamethasone

1.90 - 2.10

2.06

Benzylalcohol

14.3 -15.8

15.0

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

25 NOV 2015

Qualified Person

