



DEXDOMITOR 0,5MG/ML VET INJ1X10ML BQHURO

CERTIFICATE OF ANALYSIS

Product Number: 134810
 Batch Number: 1722079
 Order Number: 80721806
 Date of Manufacture: 09.03.2016
 Date of Expiration: 02.2019
 Storage: Room temp. +15..25°C
 Specification: Hungary (103698) 19.11.2014

| TESTS | METHOD | REQUIREMENTS | RESULTS | QUALITY CTRL SITE |
|---|----------|--------------------------|--------------------------|-------------------|
| Clarity of solution | 100182-2 | clear | clear | Esppoo |
| Colour of solution | 100182-2 | colourless | colourless | Esppoo |
| Particulate matter, presence of visible particles | 100178-2 | practically no particles | practically no particles | Esppoo |
| Volume in container | 100179-2 | 10,0 ml - 11,0 ml | 10,5 ml | Esppoo |
| pH | 100177-2 | 4,0 - 6,0 | 4,9 | Esppoo |
| Ident.: dexmedetomidine, HPLC | 100173-2 | positive | positive | Esppoo |
| Ident.: dexmedetomidine, UV | 100175-3 | positive | positive | Esppoo |
| Assay: dexmedetomidine HCl, % | 100175-3 | 95,0 % - 105,0 % | 100,6 % | Esppoo |
| Ident.: methyl parahydroxybenzoate, HPLC | 100175-3 | positive | positive | Esppoo |
| Assay: methyl parahydroxybenzoate, UV | 100175-3 | positive | positive | Esppoo |
| Ident.: methyl parahydroxybenzoate, UV | 100175-3 | 95 % - 105 % | 100 % | Esppoo |
| Ident.: propyl parahydroxybenzoate, HPLC | 100175-3 | positive | positive | Esppoo |
| Assay: propyl parahydroxybenzoate, UV | 100175-3 | positive | positive | Esppoo |
| Ident.: propyl parahydroxybenzoate, UV | 100175-3 | 95 % - 105 % | 98 % | Esppoo |
| Optical purity, levorotatorybenzoate | 100173-2 | nmt 1,0 % | < 0,5 % | Esppoo |
| Particulate matter, 10 µm or larger in count | 113289-2 | nmt 8000 | 9 | Esppoo |
| Particulate matter, 25 µm or larger in count | 113289-2 | nmt 800 | 1 | Esppoo |
| Test for sterility | 113205-1 | sterile | sterile | Esppoo |
| Bacterial endotoxins | 100590-2 | nmt 10 EU/ml | nmt 10 EU/ml | Esppoo |

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CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010
Batch Number: 1722074
Order Number: 30721808

| TESTS | METHOD | REQUIREMENTS | RESULTS | QTY CTRL SITE |
|-------|--------|--------------|---------|---------------|
|-------|--------|--------------|---------|---------------|

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 29.08.2016 16:11:27 by a Qualified Person (Kari Salonen)

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BATCH CERTIFICATE

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DEXDOMITOR 0.5MG/ML VET INJ1X10ML BQHURO

Product Number: 104010
Batch Number: 1722079
Order Number: 80721806

Date of Manufacture: 08.03.2016
Date of Expiration: 02.2019

Quantity: 260 PCE

Marketing authorization number: EU/2/02/039/001

Manufacturing site: Orion Corporation, Espoo plant

GMP Compliance of Manufact. site: 003642/06.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant

GMP Compliance of Quality Ctrl site: 003642/06.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant

GMP Compliance of Packaging site: 003642/06.08.02.00/2015

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person

Electronically approved 29.06.2018 16:11:27 by a Qualified Person Kati Salonen

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|--|--|---|---|
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|--|--|---|---|

Animal Medicinal Product Registered at the competent authority: Orionintie 1, 02200 Espoo, Finland