

Antisedan 5mg/ml oldatos injekció
 Gysz:1645538 Lej:18/01/31
 Kisz:10ml Me.:darab
 DR. SZÉKELY KFT. részére

2151 Fót
 Keleti Márton u. 19.
 Tel:27/537-100
 Fax:27/537-100



CERTIFICATE OF ANALYSIS

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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1645538
 Order Number: 80528720

Date of Manufacture: 26.01.2015
 Date of Expiration: 01.2018
 Storage: Room temp. +15...25°C
 Specification: Hungarian 100852) 04.04.2013

| TESTS | METHOD | REQUIREMENTS | RESULTS | QTY CTRL SITE |
|---|-----------|--------------------------|--------------------------|---------------|
| Colour of solution | 1004/94-2 | colourless | colourless | Espon |
| Average volume in container | 100229-2 | ml 9.0 ml | 10.5 ml | Espon |
| Volume in vial | 100229-2 | 10.0 ml - 11.0 ml | 10.5 ml | Espon |
| Particulate matter, presence of visible particles | 1004/73-2 | practically no particles | practically no particles | Espon |
| Clarity of solution | 1004/83-2 | clear | clear | Espon |
| pH | 1004/32-2 | 4.0 - 6.0 | 4.4 | Espon |
| Ident., alipamezón HCl, HPLC | 100843-3 | positive | positive | Espon |
| Ident., methyl 2-ethylhexanoate, HPLC | 100843-3 | positive | positive | Espon |
| Assay, alipamezón HCl | 100843-3 | 4.75 mg/ml - 5.25 mg/ml | 5.10 mg/ml | Espon |
| Assay, methyl parahydroxybenzoate | 100843-3 | 0.90 mg/ml - 1.10 mg/ml | 1.01 mg/ml | Espon |
| Related substances | 100843-3 | not 1.0 % | < 0.1 % | Espon |
| Test for sterility | 113206-1 | sterile | sterile | Espon |
| Bacterial endotoxins | 100850-2 | not 10 EU/ml | not 10 EU/ml | Espon |

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 2000/114/101
 Győrmező 1. sz. út 59/63
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Manufactured by contract number 0807/04/00/00/2014

Vertikális Kereskedelmi és Gyártó Kft.
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Special Preparation: Representative and Specific Characteristic: European Union



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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number:

133981

Batch Number:

1045538

Order Number:

80628720

| TESTS | METHOD | REQUIREMENTS | RESULTS | Q.LTY 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 general specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 26/03/2015 08:15:19 by a Qualified Person Vesa-Veikko Paasinen

Check Certificate Manufacturing licence number: 0012004294

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Chief Executive: Katriina Lehto, Head of Quality: Pasi Rönkä, Pharmacist: E. Rönkä