

Antisedan 5mg/ml oldatos injekció
 Gysz:1794278 Lej:20/08/31
 Kisz:10ml Me.:darab
 DR. SZÉKELY KFT. részére

2151 Fót
 Keleti Márton u. 19.
 Tel:27/537-100
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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

Product Number: 133981
 Batch Number: 1794278
 Order Number: 80812546
 Date of Manufacture: 17.08.2017
 Date of Expiration: 08.2020
 Storage: Room temp. +15..25°C
 Specification: Hungary (108652) 20.03.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100229-2	nlt 10,0 ml	10,5 ml	Espoo
Volume in cont.	100229-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Partic.matter, presence of visib. partic.	100473-2	practically no particles	practically no particles	Espoo
Clarity of solution	100493-2	clear	clear	Espoo
pH	100432-2	4,0 - 6,0	4,4	Espoo
Ident., alipamezole HCl, HPLC	100643-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, alipamezole HCl	100643-3	4,75 mg/ml - 5,25 mg/ml	5,05 mg/ml	Espoo
Assay, methyl parahydroxybenzoate	100643-3	0,90 mg/ml - 1,10 mg/ml	1,01 mg/ml	Espoo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	100650-2	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

Orion Corporation
 Manufacturing license number 002871/06.08.00.04/2015
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 Fóti Telephely
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 sz. másolat! példány
 Csak a piros szín hiteles!
 20-03



CERTIFICATE OF ANALYSIS

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TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
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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 08.09.2017 11:17:17 by a Qualified Person Katri Salonen

Orion Corporation
Manufacturing license number: 002871/06.068.00.04/2015

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Orion Corporation, Registered office and domicile: Oriontie 1, FI-02200 Espoo, Finland.

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20-03



BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1794278
Order Number: 80812546

Date of Manufacture: 17.08.2017
Date of Expiration: 08.2020

Quantity: 840 PCE

Marketing authorization number: NPV/0019/001
UP/1-322-05/13-01/856
VNRP/02/1452, 3286/1/13, 1452
LT/2/02/14/17/001, 140014
0022-1920-04.01.2013, 323-01-00026-14-001

Manufacturing site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO
005703/06.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO
005703/06.08.02.00/2015

GMP Compliance of Quality Ctrl site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO
005703/06.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant
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BATCH CERTIFICATE

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