

Antisedan 5mg/ml oldatos injekció  
 Gysz:1809256 Lej:20/09/30  
 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: 13391  
 Batch Number: 1809256  
 Order Number: 60836605  
 Date of Manufacture: 13.09.2017  
 Date of Expiration: 09.2020  
 Storage: +15-25 C  
 Specification: Hungary (108052) ZC.03.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100229-2	nmt 10.0 ml	10.5 ml	Espoo
Volume in container	100229-2	10.0 ml - 11.0 ml	10.5 ml	Espoo
Partic matter, presence of visible particles	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., atipamezole HCl, HPLC	100643-3	positive	positive	Espoo
Ident., methyl paranydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, atipamezole HCl	100643-3	4.75 mg/ml - 5.25 mg/ml	5.00 mg/ml	Espoo
Assay, methyl paranydroxybenzoate	100643-3	0.90 mg/ml - 1.10 mg/ml	1.00 mg/ml	Espoo
Related substances	100643-3	nmt 1.0 %	<0.1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	100550-2	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisations of the destination country/countries.

Electronically approved: 12/12/2017 09:08:49 by a Qualified Person Katrin Salonen

ORION P.O. Box 100 FIN-00010 HELSINKI FINLAND Tel: +358 9 4501 Fax: +358 9 4502	ORION PHARMA ZRT. P.O. Box 100 H-2151 FÓT HUNGARY Tel: +36 27 537 100 Fax: +36 27 537 100	PHOENIX PHARMA ZRT. P.O. Box 100 H-2151 FÓT HUNGARY Tel: +36 27 537 100 Fax: +36 27 537 100	PHOENIX PHARMA ZRT. P.O. Box 100 H-2151 FÓT HUNGARY Tel: +36 27 537 100 Fax: +36 27 537 100
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**PHOENIX Pharma Zrt.**  
 Fóti telephely  
 2151 Fót, Keleti M. u. 19.  
 Csak a piros szín hiteles!  
 20-03



# BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

**Product Number:** 133981  
**Batch Number:** 1809256  
**Order Number:** 89836605

**Date of Manufacture:** 13.09.2017  
**Date of Expiration:** 09.2020

**Quantity:** 1270 PCE

**Marketing authorization number:** NP.V.0019.001  
JP/1322-05/13-01/856  
VNRP/02/1452, 3260/1/13, 1452  
LT/2-02/1417/001, 140014  
0022-1920-04 01 2013, 323-01-00026-14-001

**Manufacturing site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO

**GMP Compliance of Manufact. site:** 005703-06-08 02 00/2015

**Quality control site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO

**GMP Compliance of Quality Ctrl site:** 005703-06-08 02 00/2015

**Packaging site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO

**GMP Compliance of Packaging site:** 005703-06-08 02 00/2015

Orion Corporation	Manufacturing site: Espoo plant	Quality control site: Espoo plant	Packaging site: Espoo plant
Orion Corporation Espoo Plant Oriontie 1 FI-02200 Espoo Finland	Orion Corporation Espoo Plant Oriontie 1 FI-02200 Espoo Finland	Orion Corporation Espoo Plant Oriontie 1 FI-02200 Espoo Finland	Orion Corporation Espoo Plant Oriontie 1 FI-02200 Espoo Finland

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BATCH CERTIFICATE

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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133961  
Batch Number: 180925E  
Order Number: 82836605

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 12.12.2017 09:08:49 by a Qualified Person Katrin Salonen

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20-03

Meoszám:180100487/07/T

2.pld. Kiadva: 18/09/20

Min.biz.: