

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML  
 Gysz:1896609 Lej:22/03/14  
 Kisz:10 ML Me.:Darab  
 ALPHA-VET KFT BUDAPEST részére

Medimpex Gy. Zrt.  
 1158 Budapest  
 Rákospalotaihatárút 2  
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CERTIFICATE OF ANALYSIS

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133881  
 Batch Number: 18565D8  
 Order Number: 80859888  
 Date of Manufacture: 14.03.2018  
 Date of Expiration: 03.2022  
 Storage: +15..25 °C  
 Specification: Hungary (408652) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100228-2	ml 10,0 ml	10,5 ml	Espoo
Volume in cont.	100229-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Particulate, 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., albamazole HCl, HPLC	100843-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100843-3	positive	positive	Espoo
Assay, albamazole HCl, %	100643-3	85,0 % - 105,0 %	101,1 %	Espoo
Assay, methyl parahydroxybenzoate, %	100843-3	90,0 % - 110,0 %	98,2 %	Espoo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Espoo
Tast for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins.	120383-1	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 Authorisation(s) of the destination country/countries.

Electronically approved 03.05.2019 16:00:45 by a Qualified Person Marko Kuosmanen

Orion Corporation  
 Orion Töölösä  
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 Tel. +358 10 425 1000  
 Fax +358 10 426 2435  
 Orion Corporation, English and office and domicile: Oso 20000, Finland.

Manufacturing license number: 00210006/03.03.2009  
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 HEGEDŰS KLAUDÉTTA  
 Minőségbiztosítási/vezető  
 Csak a piros szín hiteles

Meoszám: 190700053MBT

4.pld.

Kiadva: 19/10/16

Min.biz.:

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BATCH CERTIFICATE



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133951  
Batch Number: 1896609  
Order Number: 80953388

Date of Manufacture: 14.03.2018  
Date of Expiration: 03.2022

Quantity: 1920 PCE

Marketing authorization number: NPV/0019/001  
UP/1-322-05/13-01/856  
VNR/PI/02/1452, 3288/1/13, 1452  
LT/2/02/1417/001, 140014  
0022-1320-04.01.2013, 323-01-00026-14-001

Manufacturing site: Orion Corporation, Espoo plant  
Orionite 1 FI-02200 ESPOO  
GMP Compliance of Manufact. site: 00395306.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant  
Orionite 1 FI-02200 ESPOO  
GMP Compliance of Quality Ctrl site: 00395306.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant  
Orionite 1 FI-02200 ESPOO  
GMP Compliance of Packaging site: 00395306.08.02.00/2017

Orion Corporation

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Manufacturing license number: 9012020008.00.00.0219

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Csak a círes színtűvel

Meoszám:190700053MBT

4.pld. Kiadva: 19/10/16

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Gysz:1896609 Lej:22/03/14  
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### BATCH CERTIFICATE



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133281  
Batch Number: 1896609  
Order Number: 80953988

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 03.05.2018 16:00:46 by a Qualified Person Márta Kucsmanon

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Manufacturing license number: 00759028, 01.03.2019

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Csak a hitelt érdemlően

Meoszám:190700053MBT

4.pld. Kiadva: 19/10/16

Min.biz.: