

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML
 Gysz:1935798 Lej:22/11/22
 Kisz:10 ML Me.:Darab
 ALPHA-VET KFT BUDAPEST részére

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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

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Product Number: 133981
 Batch Number: 1935798
 Order Number: 80989003
 Date of Manufacture: 22.11.2019
 Date of Expiration: 11.2022
 Storage: +15,25 °C
 Specification: Hungary (108852) 11.07.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
Average volume in container	100494-2	colourless	colourless	Espoo
Volume in cont.	100228-2	ml 10,0 ml	10,5 ml	Espoo
Particulate, presence of visib. partic	100473-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Clarity of solution	100493-2	practically no particles	practically no particles	Espoo
pH	100432-2	clear	clear	Espoo
Ident., alipamezole HCl, HPLC	100643-3	4,0 - 6,0	4,4	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, alipamezole HCl, %	100643-3	95,0 % - 105,0 %	positive	Espoo
Assay, methyl parahydroxybenzoate, %	100643-3	90,0 % - 110,0 %	100,1 %	Espoo
Related substances	100643-3	nmt 1,0 %	99,3 %	Espoo
Test for sterility	113205-1	sterile	<0,1 %	Espoo
Bacterial endotoxins	120383-1	nmt 10 EU/ml	sterile	Espoo
			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 14.01.2020 13:59:14 by a Qualified Person Marko Kuosmanen

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Meoszá:200200021MBT

3.pld. Kiadva: 20/02/13

MEDIMPEX GYÓGYSZER ZRT.
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 Nagyné Kálmán biz.:
 Minőségbiztosító szakasszisztens
 Csak a piros szín hiteles

BATCH CERTIFICATE



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1935798
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Date of Manufacture: 22.11.2019
Date of Expiration: 11.2022

Quantity: 1760 POE

Marketing authorization number: NP/V/0019/001
LPI-322-05/13-01/856
V/NRP/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
Orionintie 1 FI-02200 ESPOO
GMP Compliance of Manufact. site: 003953/06.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant
Orionintie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site: 003953/06.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant
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GMP Compliance of Packaging site: 003953/06.08.02.00/2017

Orion Corporation
Manufacturing license number: FINMEA/2019/0000732

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Meoszám: 200200021MBT

3.pld. Kiadva: 20/02/13

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Nagyékei Ért. Zrt.
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles

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BATCH CERTIFICATE



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3.pld. Kiadva: 20/02/13

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Minőségbiztosító szakasszisztens
Csak a piros szín hiteles