

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML
 Gysz: 1989580 Lej: 2022-11-22
 Kisz: 10 ML Me: Darab
 SZÉKELY KFT részére

Szállító:
 Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6476
 e-mail: qa@mpx.hu

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CERTIFICATE OF ANALYSIS



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1989580
 Order Number: 81008744
 Date of Manufacture: 22.11.2019
 Date of Expiration: 11.2022
 Storage: +15..25 °C
 Specification: Hungary (108652) 11.07.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY 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., atipamezole HCl, HPLC	100643-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, atipamezole HCl, %	100643-3	95,0 % - 105,0 %	100,1 %	Espoo
Assay, methyl parahydroxybenzoate, %	100643-3	90,0 % - 110,0 %	99,3 %	Espoo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Espoo
Test 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 21.02.2020 10:59:24 by a Qualified Person Hanna Strand

Orion Corporation ORION PHARMA Oriintie 1, 02200 ESPOO P.O.Box 65, 02101 ESPOO Tel: +358 10 4261 Fax: +358 10 426 3815	Manufacturing license number: FINEA/2019/006732	Volmelaan 8, 75700 KUOPIO P.O.Box 1760, 70701 KUOPIO Tel: +358 10 428 611 Fax: +358 10 428 6444	Jousunkatu 7, 24100 SALO Tel: +358 10 4261
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Orion Corporation. Registered office and domicile, Oriintie 1, FI-02200 Espoo, Finland.

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Product Number: 133981
Batch Number: 1989580
Order Number: 81008744

Date of Manufacture: 22.11.2019
Date of Expiration: 11.2022

Quantity: 800 PCE
Strength/Potency: 5 mg/ml
Dosage form: SOLUTION FOR INJECTION
Package size: 10 ml

Marketing authorization number: NP/V/0019/001
UP/1-322-05/13-01/856
V/NRP/02/1452, 3286/1/13, 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: 0039953/06.08.02.00/2017

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

GMP Compliance of Quality Ctrl site: 0039953/06.08.02.00/2017

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

GMP Compliance of Packaging site: 0039953/06.08.02.00/2017

Orion Corporation
Manufacturing license number: FINEA230 9/000732

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