



CERTIFICATE OF ANALYSIS

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1896609
 Order Number: 80953988

Date of Manufacture: 14.03.2019
 Date of Expiration: 03.2022
 Storage: +15..25 °C
 Specification: Hungary (108852) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	DLTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Esppo
Average volume in container	100229-2	ml 10,0 ml	10,5 ml	Esppo
Volume in cont.	100229-2	10,0 ml - 11,0 ml	10,5 ml	Esppo
Partic.matter, presence of visb. partic	100479-2	practically no particles	practically no particles	Esppo
Clarity of solution	100493-2	clear	clear	Esppo
pH	100432-2	4,0 - 6,0	4,4	Esppo
Ident., atipamezole HCl, HPLC	100643-3	positive	positive	Esppo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Esppo
Assay, atipamezole HCl, %	100643-3	95,0 % - 105,0 %	101,1 %	Esppo
Assay, methyl parahydroxybenzoate, %	100643-3	90,0 % - 110,0 %	99,2 %	Esppo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Esppo
Test for sterility	113205-1	sterile	sterile	Esppo
Bacterial endotoxins.	120383-1	nmt 10 EU/ml	nmt 10 EU/ml	Esppo

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 16:00:46 by a Qualified Person Marko Kuusmanen

Orion Corporation
 Manufacturing license number: 00026006.08.00.04/2019

ORION PHARMA
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 Tel: +358 10 4261

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

Meoszárn: 190700053MBT

6.p.l.d. Kiadva: 19/10/21

MEDIMP/EX GYÓGYSZER ZRT.
 1158 Bp., Rákospalota határt 2.
 Nagyne Káthya D.I.Z.
 Minőségbiztosító szakosztás
 Csak a piros színű hiteles



BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Meoszám: 190700053MBT

Product Number: 133981
Batch Number: 1896809
Order Number: 809539888

Date of Manufacture: 14.03.2019
Date of Expiration: 03.2022

Quantity: 1920 PCE

Marketing authorization number: NP/V/0019/001
UPI/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
Orionite 1 FI-02200 ESPPO

GMP Compliance of Manufact. site: 003953/06.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPPO

GMP Compliance of Quality Ctrl site: 003953/06.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPPO

GMP Compliance of Packaging site: 003953/06.08.02.00/2017

Orion Corporation Manufacturing license number: 00316/06K.01.00.04.2019

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

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Németország határánál 2.
Nagyvágy Káti Éva
Minőségbiztosító szakasszisztens
Csak a piros színű címkékre

6. oldal. Kiadva: 19/10/21

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML
Gy.sz.: 1896609
Lej.: 22/03/14
Me.: Darab
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút 2
Tel: +36-1-414-6477
Fax: +36-1-414-6479

ANTISEDAN 5MG/ML OLDAPATOS INJEKCIÓ 10ML
Gy.sz:1896609
Kisz:10 ML
Me.:Darab
Lej:22/03/14
SZEKELY KFT részére

Medimpex Gy. Zrt.
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Rákospalotaihatárút2
Tel:+36-1-414-6477
Fax:+36-1-414-6479



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Electronically approved 03.05.2019 16:00:46 by a Qualified Person Marko Kuosmanen

Meosszám:190700053MBT

6.p.l.d. Kiadva: 19/10/21

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Csak a piros színű hiteles