



CERTIFICATE OF ANALYSIS

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 13396  
Batch Number: 1867130  
Order Number: 809C6142  
  
Date of Manufacture: 06.08.2018  
Date of Expiration: 08.2021  
Storage: +15..25 C  
Specification: Hungary 1108652124.05.2018

TESTS	METHOD	REQUIREMENTS	RESULTS	QlTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100229-2	nll 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 %	100.7 %	Espoo
Assay, methyl parahydroxybenzoate, %	100643-3	90.0 % - 110.0 %	99.7 %	Espoo
Related substances	100643-3	nmt 1.0 %	<0.1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacteria: endotoxins	100650-2	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 Authorisation(s) of the destination country/countries

Electronically approved 30.10.2018 15:03:38 by a Qualified Person Katr. Salonen

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Az eredetivel megegyező hiteles másolat

MEO: 181200299/07/T

Vásárló:

Szállító: PHOENIX Pharma Zrt.

Küldte: Tóth Zoltánné, 2019/09/23

5. Másolat

Fájl: Antisedan 5mg/ml oldatos injekció AUV-1867130

Oldal: 1 / 3



BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 13398\*  
Batch Number: 1867130  
Order Number: 80906142

Date of Manufacture: 06.08.2018  
Date of Expiration: 08.2021

Quantity: 800 PCE

Marketing authorization number: NPN:0019/001  
UPH:322-05/13-01/856  
VN:RP:02-1452, 3286/1113, 1452  
LT:2.02.1417.001, 140014  
0022-1920-04 01 2013, 023-01-00026-14-001

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

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

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

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

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

GMP Compliance of Packaging site: 003953/06.08.02.00/2017

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Orion Corporation Espoo, FIN-02200 ESPOO Oriontie 1 FI-02200 ESPOO Puhelin: +358 9 4251 Faksi: +358 9 4252	Registries Espoo, FIN-02200 ESPOO Oriontie 1 FI-02200 ESPOO Puhelin: +358 9 4251 Faksi: +358 9 4252	Orion Corporation Espoo, FIN-02200 ESPOO Oriontie 1 FI-02200 ESPOO Puhelin: +358 9 4251 Faksi: +358 9 4252	Orion Corporation Espoo, FIN-02200 ESPOO Oriontie 1 FI-02200 ESPOO Puhelin: +358 9 4251 Faksi: +358 9 4252
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**Az eredetivel megegyező hiteles másolat**

MEO: 181200299/07/T

Vásárló:

Szállító: PHOENIX Pharma Zrt.

Küldte: Tóth Zoltánné, 2019/09/23

5. Másolat

Fájl: Antisedan 5mg/ml oldatos injekció AUV-1867130

Oldal: 2 / 3



## BATCH CERTIFICATE

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### ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981  
Batch Number: 1867130  
Order Number: 60906142

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 30.10.2018 15:03:38 by a Qualified Person Katri Satonen

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Orion Corporation P.O. Box 100 00010 Vammala Finland	Orion Corporation P.O. Box 100 00010 Vammala Finland	Orion Corporation P.O. Box 100 00010 Vammala Finland	Orion Corporation P.O. Box 100 00010 Vammala Finland
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### Az eredetivel megegyező hiteles másolat

MEO: 181200299/07/T

Vásárló:

Szállító: PHOENIX Pharma Zrt.

Küldte: Tóth Zoltánné, 2019/09/23

5. Másolat

Fájl: Antisedan 5mg/ml oldatos injekció AUV-1867130

Oldal: 3 / 3