



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

Page: 1(6)

Product Number: 133981
 Batch Number: 1781904
 Order Number: 80796391

Date of Manufacture: 21.04.2017
 Date of Expiration: 04.2020
 Storage: Room temp. +15..25°C
 Specification: Hungary (108692) 20.03.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100229-2	ml 10,0 ml	10,5 ml	Espoo
Volume in cont.	100229-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Particulate matter, presence of visible particles	100473-2	practically no particles	practically no particles	Espoo
Clarity of solution	100493-2	clear	clear	Espoo
pH	100432-2	4,0 - 6,0	4,3	Espoo
Ident., alparmezoie HCl, HPLC	100643-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, alparmezoie HCl	100643-3	4,75 mg/ml - 5,25 mg/ml	4,99 mg/ml	Espoo
Assay, methyl parahydroxybenzoate	100643-3	0,90 mg/ml - 1,10 mg/ml	1,01 mg/ml	Espoo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Espoo
Test for sterility	13205-1	sterile	sterile	Espoo
Bacterial endotoxins	100650-2	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

Orion Corporation
 Orijon OY AB
 P.O. Box 100, FIN-00010
 Helsinki, Finland
 Tel: +358 9 420 3100
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Manufacturing licence number: 08971/08/2004/001/2015

Importation licence number: 08971/08/2004/001/2015

Orion Corporation, Kesäkuu 2017, Orijon OY AB, Kesäkuu 2017, Orijon OY AB, Kesäkuu 2017, Orijon OY AB

Orion Corporation, Kesäkuu 2017, Orijon OY AB, Kesäkuu 2017, Orijon OY AB, Kesäkuu 2017, Orijon OY AB

PHOENIX Pharma Zrt.
 Fóti Telephely
 2151 Fót, Keleti Márton út 19.
 sz. másolati példány
 Csak a piros szín hiteles!
 20-03



CERTIFICATE OF ANALYSIS

Page: 2/4

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1781904
Order Number: 80796391

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
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The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 26.06.2017 16:50:23 by a Qualified Person Kari Salonen

Orion Corporation
Manufacturing licence number: 003710A/0001002015

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Orion Corporation, Keskuspuutarantie 1, FIN-02100 Espoo, Finland

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2151 Fő, Keleti Márton út 19.
Egyéb azonosítási példány
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20-03



BATCH CERTIFICATE

Page: 3/4

ANTISEDAN SIMS/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1781904
Order Number: 807968391

Date of Manufacture: 21.04.2017
Date of Expiration: 04.2020

Quantity: 840 PCE

Marketing authorization number: NFV/MO/19/031
UPN: 322-05/13-01/856
VN/PP: 02/1452, 3286/113, 1452
LT/2/02/14/17/001, 140014
0022-1920-04.01.2013, 323-01-00026-14-001

Manufacturing site: Orion Corporation, Espoo plant

GMP Compliance of Manufact. site: 003642/08.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant

GMP Compliance of Quality Ctrl site: 003642/08.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant

GMP Compliance of Packaging site: 003642/06.08.02.00/2015

Orion Corporation

Manufacturing licence number: 003642/08.08.02.00/2015

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Järvenpäänkatu 7, 01100 SALO
Tel: +358 10 428

Product Information: Read the instructions and data for the product. Call 0200 250000 for help.

Orion Pharma Zrt.
Póti telephely
216. Fő, Keleti Márton út 19.
Ez másolati példány
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20-03



BATCH CERTIFICATE

Page: 4(4)

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1781904
Order Number: 90796391

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved: 26.06.2017 15:50:23 by a Qualified Person Kati Salonen

PHOENIX Pharma Zrt.
Fóti Telephely
2151 Fóti, Keleti Márton út 19.
..... sz. másolati példány
Csak a piros szín hiteles!
20-03

Order Number: **Minőségirányítási szám: 035-T03X/06-00146/003**

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Order Confirmation: Approved, Office and Domestic Distribution: 11/07/2004 (approved)