



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

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Product Number: 133981
 Batch Number: 1713513
 Order Number: 80705729
 Date of Manufacture: 14.01.2018
 Date of Expiration: 01.2019
 Storage: Room Temp. +15...25°C
 Specification: 10501889-01 (M4:108682) 20.03.2011

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espp0
Average volume in container	100229-2	n1 10.0 ml	10.5 ml	Espp0
Volume in cont.	100229-2	10.0 ml - 11.0 ml	10.5 ml	Espp0
Particulates, presence of visib. partic.	100473-2	practically no particles	practically no particles	Espp0
Clarity of solution	100483-2	clear	clear	Espp0
pH	100432-2	4.0 - 6.0	4.3	Espp0
Ident., dipropazola HCl, HPLC	100543-3	positive	positive	Espp0
Ident., methyl parathydroxybenzoate, HPLC	100543-3	positive	positive	Espp0
Assay, aligamexole HCl	100543-3	4.75 mg/ml - 5.25 mg/ml	5.04 mg/ml	Espp0
Assay, methyl parathydroxybenzoate	100543-3	0.90 mg/ml - 1.10 mg/ml	1.01 mg/ml	Espp0
Related substances	100543-3	n1 1.0 %	<0.1 %	Espp0
Test for sterility	113205-1	sterile	sterile	Espp0
Bacterial endotoxins	108650-2	n1 10 EU/ml	n1 10 EU/ml	Espp0

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 Drogen-Exportation: 4, Aggortó utca 24. kerület, Péterfy központ, Péterfy központ, Péterfy központ

Antisedan 5mg/ml oldatos injekció
 Gysz:1713513 Lej:19/01/31
 Kisz:10ml Me.:darab
 DR. SZÉKELY KFT. részére



ANTISEDAN 5MG/ML VET INJ 100ML HUEN

BATCH CERTIFICATE

Product Number: 433981
 Batch Number: 1713513
 Order Number: 80758729

Date of Manufacture: 14.01.2018
 Date of Expiration: 01.2019

Quantity: 900 PCE

Marketing authorization number: NPNV/00194901
 U/P1: 322.05/13.07/856
 VNRP/02/14/2014.1482
 LTR/02/14/2014.140014
 0022-1920-04.01.2013.323-01-00024-14-001

Manufacturing site: Orion Corporation, Espoo plant
 Certificate 1 FI-02200 ESP00
 GMP Compliance of Manufact. site: 003642/05.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant
 Certificate 1 FI-02200 ESP00
 GMP Compliance of Quality Ctrl site: 003642/05.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant
 Certificate 1 FI-02200 ESP00
 GMP Compliance of Packaging site: 003642/05.08.02.00/2015

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 Tel: +358 10 420

Quart. Formation, Regional office and domestic cooperation: L. P. 02200 Espoo, Finland

Antisedan 5mg/ml vet inj 100ml huen
 Batch certificate
 No. 1713513
 Order no. 80758729
 Date of manufacture: 14.01.2018
 Date of expiration: 01.2019
 Quantity: 900 PCE



CERTIFICATE OF ANALYSIS

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ANTISEDAN SRINGIL VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1713513
 Order Number: 00706729

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 26.04.2016 12:19:19 by a Qualified Person Kati Salonen

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Manufacturing licence number: 00017390, 04.06.2015

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PROBENIX Pharma 2016
 Főli telephely
 2161 Fót, Keleti Márton út 19
 sz. másolat példány
 Csak a piros színű hitelesítéssel
 érvényes.



ANTISEDAN SINGIL VET INU 10ML/100EN

BATCH CERTIFICATE

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Product Number: 133891
 Batch Number: 1713513
 Order Number: 80705729

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 26.04.2016 12:19:19 by a Qualified Person Kati Salonen

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Dr. Katalin Szabó Zrt.
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 ex. másolat példány
 a kócskafti helyen
 2020