



CERTIFICATE OF ANALYSIS

Page 1/3

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1859256
 Order Number: 60836605
 Date of Manufacture: 13.09.2017
 Date of Expiration: 09.2020
 Storage: +15 - 25 C
 Specification: Hungary (106652): 2C.03.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY 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
Partic mater. presence of visio. 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. alipamezole HCl. HPLC	100643-3	positive	positive	Espoo
Ident. methyl paratydroxybenzoate. HPLC	100643-3	positive	positive	Espoo
Assay. alipamezole HCl	100643-3	4.75 mg/ml - 5.25 mg/ml	5.00 mg/ml	Espoo
Assay. methyl paratydroxybenzoate	100643-3	0.90 mg/ml - 1.10 mg/ml	1.00 mg/ml	Espoo
Related substances	100643-3	nmt 1.0 %	<0.1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial 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 Authorisations of the destination country/countries.

Electronically approved 12/12/2017 09:08:49 by a Qualified Person Katri Satonen

ALPHA-VET ÁLLATGYŰGY. KFT.
 106652, Fót, Keleti Márton u. 19.
 Tel: +36 (27) 537 100
 Fax: +36 (27) 537 100

ANTISEDAN 5MG/ML VET INJ 10ML HUEN
 106652, Fót, Keleti Márton u. 19.
 Tel: +36 (27) 537 100
 Fax: +36 (27) 537 100

ALPHA-VET ÁLLATGYŰGY. KFT.
 106652, Fót, Keleti Márton u. 19.
 Tel: +36 (27) 537 100
 Fax: +36 (27) 537 100

ALPHA-VET ÁLLATGYŰGY. KFT.
 106652, Fót, Keleti Márton u. 19.
 Tel: +36 (27) 537 100
 Fax: +36 (27) 537 100

PHOENIX Pharma Zrt.
 Fóti telephely
 2151 Fót, Keleti M. u. 19.
 Csak a piros szín hiteles!
 20-03