



CERTIFICATE OF ANALYSIS

DOMOSEBAN GEL 7.6 MG/ML VET 1X3ML PL HU

Product Number: 128659  
Batch Number: 1886525  
Order Number: 80944576  
Date of Manufacture: 01.02.2019  
Date of Expiration: 01.2022  
Storage: +15, 25 °C  
Specification: Hungary (125875) 20.06.2016

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
State	114487-2	even, translucent gel	even, translucent gel	Turku
Colour	114487-2	blue	blue	Turku
Air bubbles	114487-2	essentially free	essentially free	Turku
Uniformity of dosage units	114439-3	conforms to Ph.Eur.	conforms to Ph.Eur.	Turku
Uniform. of dos. units, accept. val.	114439-3	nmt 15.0	0.5	Turku
pH	114489-1	5.0 - 6.2	6.1	Turku
Viscosity	114488-2	6000 cP - 17000 cP	11000 cP	Turku
Identification, delonidine, HPLC	114439-3	positive	positive	Turku
Ident., delonidine, UV	114439-3	positive	positive	Turku
Ident., blue colour	114447-2	positive	positive	Turku
Related substances, individuals	114439-3	nmt 0.5 %	<0.1 %	Turku
Related substances, total	114439-3	nmt 1.0 %	<0.1 %	Turku
Assay, delonidine HCl	114439-3	95.0 % - 105.0 %	101.2 %	Turku

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 07.03.2019 14:24:37 by a Qualified Person Satu Ahvas

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DOMOSEBAN GEL 7,6MG/ML 1X3ML  
Gysz: 1886525  
Kisz: 1X3ML  
SZÉKELY KFT részére  
Lej: 22/01/31  
Me.: Doboz

Medimpex Gy. Zrt.  
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## BATCH CERTIFICATE

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**DOMOSÉDAN GEL 7.6 MG/ML VET 1X3ML PL HU**

Product Number: 128659  
Batch Number: 1886525  
Order Number: 80944576

Date of Manufacture: 01.02.2019  
Date of Expiration: 01.2022

Quantity: 250 PCE

Marketing authorization number: 2518/109/MGSSZH ATT  
1907/09

Manufacturing site: Orion Corporation, Turku plant  
Tengströminkatu 8 20360 TURKU  
GMP Compliance of Manufact. site: 005065/06.08.02.00/2015

Quality control site: Orion Corporation, Turku plant  
Tengströminkatu 8 20360 TURKU  
GMP Compliance of Quality Ctrl site: 005065/05.08.02.00/2015

Packaging site: Orion Corporation, Turku plant  
Tengströminkatu 8 20360 TURKU  
GMP Compliance of Packaging site: 005065/06.08.02.00/2015

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Meosszám: 190700004MBT

4. pld., Kiadva: 19/12/05

MEDIMPÉX GYÓGYSZER ZRT.  
1158 Bp., Munkácsy Mihály utca 2.  
Nagyvárdi Kán Éva  
Minőségbiztosító szakasszisztens  
Csak a proszín hiteles

DOMOSÉDAN GEL 7,6MG/ML 1X3ML  
Gysz: 1886525  
Kész: 1X3ML  
SZEKELY KFT részére  
Lej: 22/01/31  
Me.: DoboZ

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