



CERTIFICATE OF ANALYSIS

DOMOSSEDAN 10MG/ML VET INJ 5ML HU EN

Product Number: 133975
 Batch Number: 1654653
 Order Number: 80638775

Date of Manufacture: 17.11.2014
 Date of Expiration: 11.2017
 Storage: Room temp: +15..25°C
 Specifications: Hungary(080640) 22.10.2008

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Volume in cont.	100477-2	5.00 ml - 5.75 ml	5.20 ml	
Clarity of solution	100493-2	clear	clear	
Colour of solution	100494-2	colourless	colourless	
Particulate: pres. of foreign partic.	100473-2	practically no particles	practically no particles	
pH	100482-2	4.0 - 5.5	4.3	
Ident., decomposition HCl, HPLC	100642-4	positive	positive	
Assay, determination HCl	100642-4	9.5 mg/ml - 10.5 mg/ml	10.2 mg/ml	
Ident., methyl parahydroxybenzoate, HPLC	100642-4	positive	positive	
Assay methyl parahydroxybenzoate	100642-4	0.9 mg/ml - 1.1 mg/ml	1.0 mg/ml	
Related substances	100642-4	mt: 1 %	mt: 1 %	
Test for sterility	113205-1	sterile	sterile	
Bacterial endotoxins	100970-2	mt: 25 EU/ml	mt: 25 EU/ml	

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 15.05.2015 07:32:06 by a Qualified Person Viki Verku Pasanen

Orion Corporation Manufacturing licence number 000783636 05.05.01/2014

DR. SZÉKELY KFT.
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Tempervárható, 500ml TERNALI
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 Tel: 27/537-100

Pracovník Pharmax Zrt.
 F6t Tolophely
 2151 F6t, Keleti Márton u. 19.
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 ... a tpe sán hítoe
 2015



BATCH CERTIFICATE

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DOMOSEDAN 10MG/ML VET INJ 5ML HU EN

Product Name: 133975
Batch Number: 1654653
Order Number: 80836775

Date of Manufacture: 17.11.2014
Date of Expiry: 11.2017

Quantity: 500 PCE

Marketing authorization number:

UPH-322-05/13-01/055
140013, NIP/V0004/001, 1454
20791406, LT/2012/416/001
VIMR/024/451
0022-1918-04 01 2013, 323-01-00028-14-001

Manufacturing site:

Orion Corporation, Espoo Plant
Oskariatie 3 FI-02200 ESPOO
12212.01.01/2014

Packaging site:

Orion Corporation, Espoo Plant
Oskariatie 3 FI-02200 ESPOO
12212.01.01/2014

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 15.05.2016 07:32:06 by: a Qualified Person Ville Veikko Pesonen

Orion Corporation

Manufacturing licence number: 0003636 on 01.04.2014

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Orion Corporation, Department: Office and Materials - Development 1, P.O. Box 1000, Espoo, Finland

Min. egészségügyért
2016. évi. Keresletkérő kiírás
2016. évi. Keresletkérő kiírás
2016. évi. Keresletkérő kiírás
2016. évi. Keresletkérő kiírás