



CERTIFICATE OF ANALYSIS

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DOMOSSEDAN 10MG/ML VET INJ 5ML HU EN

Product Number: 133973
 Batch Number: 1540161
 Order Number: 80495495

Date of Manufacture: 08.04.2013
 Date of Expiration: 04.2016
 Storage: Room temp. +15...25°C
 Specification: Hungary/1055690/22.10.2008

TESTS	METHOD	REQUIREMENTS	RESULTS
Volume in cont.	100477-2	5,00 ml - 5,75 ml	5,10 ml
Clarity of solution	100493-2	clear	clear
Colour of solution	100494-2	colourless	colourless
Particulate matter, pres. of foreign partic. matter	100473-2	practically no particles	practically no particles
pH	100432-2	4,0 - 5,5	4,3
Ident., delonidine HCl, HPLC	100562-4	positive	positive
Assay, delonidine HCl	100582-4	9,5 mg/ml - 10,5 mg/ml	10,0 mg/ml
Ident., methyl parahydroxybenzoate, HPLC	100542-4	positive	positive
Assay methyl parahydroxybenzoate	100842-4	0,9 mg/ml - 1,1 mg/ml	1,0 mg/ml
Related substances	100542-4	nmt 1 %	nmt 1 %
Test for sterility	113205-1	sterile	sterile
Bacterial endotoxins	108570-2	nmt 25 EU/ml	nmt 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.

Electrically approved 11.07.2013 14:44:31 by a Qualified Person Csiko Lehelten

Owner Corporation

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