



Das Tierarztunternehmen.

Wirtschaftsgenossenschaft
deutscher Tierärzte eG

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Certificate of Analysis	
Date	11.09.2017
Created at	10:04:38 AM
Customer no.	

Page:

1 / 2

Material: 25652
Description: Apomorphinhydrochlorid Lsg. 0,5%
Packing unit: 5 x 1 ml (WDT)

Batch: 0010517
Expiry date: 11.2018 Manufacturing date:

Parameter	Unit	Value	Lower Limit	Upper Limit
imprint batch no. and date of expiry		complies	-	-
appearance	Unit	complies	-	Upper Limit
primary packaging material	Unit	complies	-	Upper Limit
secondary packaging material	Unit	complies	-	Upper Limit
colour (EP, 2.2.2)	Unit	complies	-	Upper Limit
clarity (EP, 2.2.1)	Unit	complies	-	Upper Limit
visible particles	Unit	complies	-	Upper Limit
pH value (CoA)	Unit	4,7	4,0	5,0
relative density (CoA)	Unit	1,000	0,990	1,010
extractable volume (CoA)	Unit	1,08	1,00	1,15
ident apomorphine hydrochloride (CoA)	Unit	complies	-	Upper Limit
ident sodium metabisulfite (CoA)	Unit	complies	-	Upper Limit
apomorphine hydrochloride (CoA)	Unit	5,14	4,75	5,25
sodium metabisulfite (jodometric)(CoA)	Unit	0,96	0,90	1,10

Board of Directors Dr. Joachim Lattmann, Dr. Thomas Nonnewitz, Olaf Assenheimer
Supervisory Board Dr. Christian Siedentopf, Chairman
Registered Head Office Garbsen
Registration Court Amtsgericht Hannover, GnR 11 00 09 USt-IdNr. DE 115657322

Sparkasse Hannover Account No.900 095 019, BLZ 250 501 80
IBAN DE59 2505 0180 0900 0950 19, BIC SPKH DE 2H
Hannoversche Volksbank Account No.610 440 59 00, BLZ 251 900 01
IBAN DE12 2519 0001 6104 4059 00, BIC VOHA DE 2H

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Parameter	Unit	Value	Lower Limit	Upper Limit
unk. impurity, single (CoA)	%	0,100	-	0,200
unk. impurities, total (CoA)	%	0,300	-	0,800
sterility (EP, 2.6.1) (CoA)	Unit	Value complies	Lower Limit -	Upper Limit -
bact. endotoxins (EP, 2.6.14) (CoA)	Unit	Value I.U./ml < 3,0	Lower Limit -	Upper Limit 3,0
text ref. to print approval	Unit	Value complies	Lower Limit -	Upper Limit -
layout ref. to print approval	Unit	Value complies	Lower Limit -	Upper Limit -
print colours ref. to print approval	Unit	Value complies	Lower Limit -	Upper Limit -

The above mentioned batch has been manufactured and checked in accordance with the requirements of its Marketing Authorization, in accordance with the principles and guidelines of EU GMP, German Drug Law and German Drug Manufacturing Regulation. It conforms to all specifications and is released to the market hereby.

The approval was made by electronic signature of Dr. Andreas Benen, Sachkundige Person / Qualified Person, plant Garbsen, on Jul 20, 2017, 3:51:04 PM. This document was generated from a computer-based system validated pursuant to annex 11 of the EU GMP Guide. The data in this document, as well as the documented decision to release are legally valid without a manual signature in full.