CERTIFICATE OF ANALYSIS

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Product: **Apomorphinhydrochlorid-Lösung 0,5 % (WDT)**
Material no.: 00313
Batch number: 015016
Manufacturing date: 08.01.16
Expiration date: 07/2017
Container: 5 ampouls of 1 ml

Parameter	Specification	Result
Analysis		
General		
text, layout and product insert	complies	complies
imprint (batch number and date of expiry) is correct	complies	complies

Parameter	Specification	Result
Analysis		
General		
text, layout and product insert (regulatory affairs)	complies	complies
certificate of analysis (ref. to test profil)	current COA corresponds with the reference COA	complies
appearance	solution	complies
appearance and colour (EP, chapter 2.2.2) (COA)	complies reference solution1	complies
appearance and clarity (EP, chapter 2.2.1) (COA)	not more coloured than colorimetric solution B6	complies
visible particles (EP, chapter 2.9.20) (COA)	free of particles	complies
absolute density (EP, chapter 2.2.5) (COA)	0.99 - 1.01 g/ml	1.00 g/ml
pH value (EP, chapter 2.2.3) (COA)	4.0 - 5.0	4.2
withdrawable volume (EP, chapter 2.9.17) (COA)	1.00 - 1.15 ml	1.08 ml

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Parameter	Specification	Result
primary packaging material	clear glass ampoule	complies
Identity		
apomorphine hydrochloride (COA)	HPLC: t(R) sample and reference are comparable	complies
sodium metabisulfite (EP, chapter 2.3.1 a) (COA)	white precipitation	complies
Assay		
apomorphine hydrochloride (COA)	4.75 - 5.25 mg/ml	5.07 mg/ml
sodium metabisulfite (iodometric) (COA)	0.90 - 1.10 mg/ml	0.95 mg/ml
Purity		
unknown impurity, single (ref. to apomorphine HCl) (COA)	<= 0.2 %	0.2 %
unknown impurities, total (ref. to apomorphin HCl)(COA)	<= 0.8 %	0.4 %
Microbiology		
General		
Sterility (EP, chapter 2.6.1) (COA)	sterile according to EP, chapter 2.6.1	complies
bacterial endotoxins (EP, chapter 2.6.14) (AZ)	<= 3.0 IU/ml	<3.0 IU/ml

Status Finished product : Effective

Status Half finished product: Cancelled

The batch release in LIMS was executed on 17.3.16-10:13 by electronic signature of
Dr. Andreas Benen, Qualified Person, WDT eG, Plant Berenbostel.

LIMS is a computerised system. It is valid in accordance to EU GMP Guidelines, Annex 11. This certificate of analysis has been generated by LIMS.

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The data in this document, as well as the documented decision of the batch release, are fully valid without manual signature.