CERTIFICATE OF ANALYSIS

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Product: **Apomorphinhydrochlorid-Lösung 0,5 % (WDT)**
Material no.: 00313
Batch number: 016066
Manufacturing date: 23.06.16
Expiration date: 12/2017
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
date of manufacture (COA)	Herstelldatum v. Solupharm GmbH	complies
appearance	solution	complies
appearance and colour (EP, chapter 2.2.2) (COA)	not more coloured than colorimetric solution B6	complies
appearance and clarity (EP, chapter 2.2.1) (COA)	complies to reference solution 1	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
withdrawable volume (EP, chapter 2.9.17) (COA)	1.00 - 1.15 ml	1.06 ml

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pH value (EP, chapter 2.2.3) (COA)	4.0 - 5.0	4.1
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	5.16 mg/ml
sodium metabisulfite (iodometric) (COA)	0.90 - 1.10 mg/ml	0.98 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

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The above mentioned batch complies with Marketing Authorization, German Drug Law, German Drug Manufacturing Regulation and EU GMP Guidelines.

Finished product

- complies with the specification
- is released for the market

The batch release in LIMS was executed on 24.8.16-10:38 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. The data in this document, as well as the documented decision of the batch release, are fully valid without manual signature.