



## Certificate of Analysis

FARMADENT d.o.o.	
Minarikova ul. 6	
2000 Maribor	
Projek: FUJS DRAGO	
<i>[Signature]</i>	
Datum prejema:	30.5.14.
Prejedak:	MAKOLT Robert, mag. farm., spec.
<i>[Signature]</i>	
Datum pregleda:	30.5.14.

Productname: **Morphini hydrochloridum**  
Number of analysis/Inspection Code: 1 / KEUR-97749B  
Batchnumber: **12F21-B01-283771** ✓  
Reference code / No.: 1242 / 12-00325  
Analysed according to: **PH.EUR7.5+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear / $\leq Y_6$ or $B Y_6$	Conform		2% $m/V$
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-110 - -115	-114	°	2% $m/V$ ; dried
Related substances	Conform	Conform		HPLC
Impurity B	$\leq 0,4$	0,1	%	
Impurity C	$\leq 0,2$	$< 0,05$	%	
Impurity E	$\leq 0,2$	$< 0,05$	%	
Any other impurity	$\leq 0,2$	0,2	%	
Total impurities	$\leq 1,0$	0,4	%	
Water (Karl Fischer)	12,5 - 15,5	14,0	%	
Sulphated ash	$\leq 0,1$	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Morphine hydrochloride	98,0 - 102,0	100,3	% $m/m$	Dried
Particle size	97% $< 125 \mu m$	Conform	%	Microscopy
Total aerobic microbial count (TAMC)	$\leq 10$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 1$	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Synergy Health+Microbiologie.

Release:  
Drs. M.V. Garcia Alia  
Pharmacist - QA Manager / QP

16-07-13

Expiration: 04-2016 ✓

Conclusion: APPROVED

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