



## Certificate of Analysis

Productname: **Homatropini hydrobromidum**  
Number of analysis/Inspection Code: **1 / KEUR-102803B**  
Batchnumber: **13K29-B12-288859**  
Reference code / No.: **3420 / 1055129**  
Analysed according to: **PH.EUR 7.8**

<b>FARMADENT d.o.o.</b> Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO
Datum prejema: <u>24.4.14</u>
Pregledal: <u>MAROLT Robert, mag. farm. spec.</u>
Datum pregleda: <u>25.4.2014</u>

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or	Conform		
Appearance	Colourless crystals	Conform		
Melting point	Ca. 215	214	°C	With decomposition; data producer
Identification A	Conform	Conform		IR-spectrum
Identification C	White yellow	Conform		Bromide
Appearance of solution	Clear and colourless	Conform		5% <i>m/V</i>
pH	5,0 - 6,5	5,3		5% <i>m/V</i>
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	0,2	%	
Impurity B	<=0,1	n.d.	%	
Impurity C	<=0,1	<0,05	%	
Impurity D	<=0,1	n.d.	%	
Any other impurity	<=0,1	<0,05	%	
Total impurities	<=1,0	0,2	%	
Loss on drying	<=0,5	0,2	%	105 °C
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Homatropine hydrobromide	99,0 - 101,0	100,8	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Proxylabs.

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

12/27/13

Expiration: 06-2016

Conclusion: APPROVED

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