



Certificate of Analysis



Productname: **Methacholinii chloridum**
Number of analysis/Inspection Code: 2 / KEUR-108711B
Batchnumber: **14D15-B05-293978** ✓
Reference code / No.: 2462 / 135000B
Analysed according to: **DAC 2008**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals; hygroscopic	Conform		
Identification A	Conform	Conform		TLC
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		Chloride
Appearance of solution	Clear / colourless	Conform		2% <i>m/V</i>
pH	4,0 - 6,0	4,6		2% <i>m/V</i>
Related substances	Conform	Conform		HPLC; data producer
Impurity A	<=0,5	0,0	%	
Impurity B	<=0,5	0,0	%	
Impurity C	<=0,5	0,0	%	
Impurity D	<=0,5	0,0	%	
Impurity E	<=0,5	0,0	%	
Impurity F	<=0,5	0,0	%	
Any other impurity	<=0,1	0,0	%	
Sum of all impurities other than A	<=1,5	0,0	%	
Water (Karl Fischer)	<=1,5	0,6	%	
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Methacholine chloride	98,0 - 100,5	99,6	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Eurofins Parijs.

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

06/05/14

Expiration: 04-2018 ✓

Conclusion: APPROVED