

## Certificate of Analysis

**Productname:** Bupivacaini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-179342B  
**Batchnumber:** 18C28-B03-365990  
**Reference code / No.:** 4171 / 17J56N11  
**Analysed according to:** PH.EUR 9.4

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder or colorless crystals	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chloride
Identification E	-0,10 - +0,10	Conform	°	Optical rotation
Appearance of solution	Clear and colourless	Conform		2% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Optical rotation	-0,10 - +0,10	-0,00	°	
Related substances	Conform	Conform		GC
Impurity B	<=0,5	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=1,0	<1,0	%	
2,6- Dimethylaniline	<=10	1	ppm	
Loss on drying	4,5 - 6,0	5,3	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Bupivacaine hydrochloride	98,5 - 101,0	100,0	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:  
 dr. M.J. Vincenten - van Maanen  
 Pharmacist - Qualified Person

01/06/20

Expiration: 08-2022

Conclusion: APPROVED

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