

Certificate of Analysis

Product name: **Bupivacaini hydrochloridum**
Batch number / Weight: **21J11-B06-216164 / 100 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Identification E	-0,10 - +0,10	Conform	°	
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Optical rotation	-0,10 - +0,10	-0,02	°	
Related substances	Conform	Conform		
Impurity B	<=0,5	<0,02	%	
Any other impurity	<=0,10	<0,10	%	
Total impurities	<=1,0	<1,0	%	
2,6- Dimethylaniline	<=10	<10	ppm	
Loss on drying	4,5 - 6,0	5,1	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Bupivacaine hydrochloride	98,5 - 101,0	99,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

28-02-2022

Expiration: 30-06-2025

Conclusion: APPROVED

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