

Certificate of Analysis

Productname: Bupivacaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-186502B
Batchnumber: 20F18-F06-374039
Reference code / No.: 4171 / 20E56N02
Analysed according to: PH.EUR10.2

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%m/V
Acidity or alkalinity	Conform	Conform		
Optical rotation	-0,10 - +0,10	-0,01	°	
Related substances	Conform	Conform		GC
Impurity B	<=0,5	<0,5	%	
Any other impurity	<=0,10	<0,10	%	
Total impurities	<=1,0	<1,0	%	
2,6- Dimethylaniline	<=10	7	ppm	HPLC
Loss on drying	4,5 - 6,0	5,3	%	105°C
Sulphated ash	<=0,1	0,1	%	
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	100,3	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/21/20

Expiration: 04-2025

Conclusion: APPROVED

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