Certificate of Analysis

Product name: **Bupivacaini hydrochloridum**

Batch number / Weight: **21J11-B06-224412 / 100 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21J11-B06 / INS-21-5838**

Reference Code / No.: **V01788 / 20G56N06**

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, Eurofins

Release:
Ewelina Gadzinowska
Qualified Person

27-10-2022

Expiration: 30-06-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl