

Certificate of Analysis

Product name: Lidocaini hydrochloridum monohydricum

Batch number: 19E22-B01-192180

Base unit: 5g

Expiration date: 29.02.2024

Quality: Ph.Eur.

Manufacturing date: 26.08.2019

Inspection report no.: INS-19-02344

IIN: 100650-114-91

Parameter	Limit value	Result	Unit	Laboratory
Appearance	white or almost white, crystalline powder	conform		
Identification B	acc. to Ph. Eur.	conform		
Identification D	acc. to Ph. Eur.	conform		
Appearance of solution	acc. to Ph. Eur.	conform		
pH	4,0 - 5,5	5,20		
Related substances	- impurity A: max. 0,01% - unspecified impurities: max. 0,10% - total: max. 0,5%	0,0005 0,05 0,05	%	
Water	5,5 - 7,0%	6,36	%	
Sulphated ash	max. 0,1%	0,01	%	
Assay	99,0 - 101,0%	100,79	%	
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
Elemental impurities	CHMP/ICH/353369/2013	conform		data producer
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory: Fagron Poland

Release:

Dorota Sutkowska

Qualified Person



Fagron sp. z o.o.

Dorota Sutkowska

osoba wykwalifikowana
qualified person

Date of releasing: 07.09.2019

Conclusion: Approved