

Certificate of Analysis

Product name: **Furosemidum**

Batch number / Weight: **23G05-B14-230411 / 10 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23G05-B14 / INS-23-6304**

Reference Code / No.: **V01391 / FSM-1E-232018**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / \leq BY5	Conform		
Related substances	Conform	Conform		
Impurity C	$\leq 0,2$	0,05	%	
Impurity D	$\leq 0,15$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,5$	0,05	%	
Chlorides	≤ 200	< 200	ppm	
Sulphates	≤ 300	< 300	ppm	
Loss on drying	$\leq 0,5$	0,12	%	
Sulphated ash	$\leq 0,1$	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	99,77	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	$\leq 10^3$	$< 10^2$	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 10	CFU/g	

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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 lab

Release:
Ewelina Gadzinowska
Qualified Person

02-10-2023

Expiration: 31-03-2028

Conclusion: APPROVED

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