

Certificate of Analysis

Product name: **Furosemidum**

Batch number / Weight: **21G14-B06-216821 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / <=BY5	Conform		
Related substances	Conform	Conform		
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,05	%	
Chlorides	<= 200	Conform	ppm	
Sulphates	<= 300	Conform	ppm	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<= 0,1	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	99,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	105	ppm	
Ethanol	<=5000	<10	ppm	
Propan-2-ol	<=5000	23	ppm	
Ethyl acetate	<=5000	27	ppm	
Methyl acetate	<=5000	<10	ppm	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

23-02-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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