

Certificate of Analysis

Productname: Furosemidum
Number of analysis/Inspection Code: 1 / KEUR-179111B
Batchnumber: 19I27-F04-366899
Reference code / No.: 2620 / FUR-1A-192016
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=BY5	Conform		
Related substances	Conform	Conform		HPLC
Impurity C	<=0,2	0,06	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,1	%	
Chlorides	<= 200	Conform	ppm	
Sulphates	<= 300	Conform	ppm	
Loss on drying	<=0,5	0,1	%	105 °C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Furosemide	98,5 - 101,0	100,7	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

12/24/19

Expiration: 02-2024

Conclusion: APPROVED

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