

Certificate of Analysis

Product name: **Sildenafil citras**
Batch number / Weight: **19K12-B01-196795 / 1 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Identification	Conform	Conform		
Impurity E	<=0,1	<0,1	%	
Related substances	Conform	Conform		
Impurity A	<=0,15	0,0	%	
Impurity D	<=0,15	0,0	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=0,5	0,06	%	
Water	<=2,5	1,29	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sildenafil citrate	98,0 - 102,0	100,6	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

27-04-2020

Expiration: 30-06-2024

Conclusion: APPROVED

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