

Certificate of Analysis

Product name: Sildenafil citras
Batch number / Weight: 19B07-B02-194720 / 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	$\leq 0,1$	$< 0,1$	%	
Related substances	Conform	Conform		
Impurity A	$\leq 0,15$	$< 0,05$	%	
Impurity D	$\leq 0,15$	$< 0,15$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,5$	$< 0,5$	%	
Water	$\leq 2,5$	1,2	%	
Sulphated ash	$\leq 0,1$	0,0	%	
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	101,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

28-10-2019

Expiration: 30-04-2023

Conclusion: APPROVED

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