

Certificate of Analysis

Product name: Chlorhexidini diacetat
Batch number / Weight: 22C12-B01-217479 / 25 G
Analysed according to: Ph. Eur. 10.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, microcrystalline powder	Conform		
Identification A	Conform	Conform		
Impurity P (chloroaniline)	<=500	< 500 ppm		
Related substances	Conform	Conform		
Sum of impurities I and O	<=0,4	<0,05	%	
Impurity A	<=0,15	<0,05	%	
Impurity H	<=0,15	0,047	%	
Impurity N	<=0,15	<0,05	%	
Impurity K	<=0,3	0,061	%	
Unspecified impurities	<=0,10	<0,05	%	
Total	<=0,8	0,108	%	
Loss on drying	<=3,5	2,57	%	
Sulfated ash	<=0,15	0,01	%	
Assay	98,0 - 101,0	99,57	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000	<3000	ppm	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-08-2022

Expiration: 24-01-2027

Conclusion: APPROVED

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