

Certificate of Analysis

Product name: **Chlorhexidini diacetat**
Batch number / Weight: **22C12-B01-226324 / 25 G**
Analysed according to: **Ph.Eur.11**
Number of analysis / Inspection Code **22C12-B01 / INS-22-4682**
Reference Code / No.: **V01830 / A-220023**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, microcrystalline powder	Conform		
Identification A	Conform	Conform		
Chloroaniline	≤ 500	60,47	ppm	
Related substances	Conform	Conform		
Sum of impurities I and O	$\leq 0,4$	$< 0,05$	%	
Impurity A	$\leq 0,15$	$< 0,05$	%	
Impurity H	$\leq 0,15$	0,047	%	
Impurity N	$\leq 0,15$	$< 0,05$	%	
Impurity K	$\leq 0,3$	0,061	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total	$\leq 0,8$	0,108	%	
Loss on drying	$\leq 3,5$	2,57	%	
Sulfated ash	$\leq 0,15$	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	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

25-01-2023

Expiration: 24-01-2027

Conclusion: APPROVED

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