

Certificate of Analysis

Productname: Chlorhexidini diacetat
Number of analysis/Inspection Code: 1 / KEUR-183107B
Batchnumber: 19F27-B03-369052
Reference code / No.: 4114 / A-190235
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, micro crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Chloroaniline	<=500	Conform	ppm	
Related substances	Conform	Conform	%	HPLC
Sum of impurities I and O	<=0,4	0,1	%	
Impurity K	<=0,3	0,2	%	
Impurity A,H, N	<=0,15	0,07	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,8	0,4	%	
Loss on drying	<=3,5	2,4	%	105°C
Sulphated ash	<=0,15	0,01	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Chlorhexidine diacetate	98,0 - 101,0	99,7	%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:
Wai Lung Chung
Pharmacist - Qualified Person

06/03/20

Expiration: 05-2024

Conclusion: APPROVED

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