

Certificate of Analysis

Product name: **Tretinoinum**

Batch number / Weight: **21G10-B08-213969 / 5 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	yellow or light orange, crystalline powder	Conform		
Identification A	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,5$	0,12	%	
Unspecified impurities	$\leq 0,2$	0,15	%	
Total impurities	$\leq 1,0$	0,41	%	
Loss on drying	$\leq 0,5$	0,06	%	
Sulphated ash	$\leq 0,1$	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	101,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Ethyl acetate	≤ 5000	<5000	ppm	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

17-12-2021

Expiration: 09-11-2023

Conclusion: APPROVED

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