

Certificate of Analysis

Product name: **Tretinoinum**
Batch number / Weight: **22A22-B03-217084 / 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	$\leq 0,5$	$< 0,05$	%	
Unspecified impurities	$\leq 0,2$	0,06	%	
Total impurities	$\leq 1,0$	0,13	%	
Loss on drying	$\leq 0,5$	0,01	%	
Sulphated ash	$\leq 0,1$	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	99,71	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Total aerobic microbial count (TA)		< 10	CFU/g	
Total yeasts and moulds (TYMC)		< 10	CFU/g	
Residual solvents				
Ethyl acetate	≤ 5000	< 5000	ppm	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

30-05-2022

Expiration: 01-08-2024

Conclusion: APPROVED

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