

Certificate of Analysis

Product name:	Tretinoinum
Batch number / Weight:	21G10-B08-213337 / 1 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	<=0,5	0,12	%	
Unspecified impurities	<=0,2	0,15	%	
Total impurities	<=1,0	0,41	%	
Loss on drying	<=0,5	0,06	%	
Sulphated ash	<=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: Residual solvents	No contamination with TSE/BSE-risk materials	Conform		
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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Fagron sp. z o.o. ul. Pasternik 26, 31-354 Kraków, Poland tel.: +48 12 3343 512 e-mail: biuro@fagron.pl