

Certificate of Analysis

Product name: Tretinoinum
Batch number / Weight: 25G29-B03-014641 / 5 g
Producer / Producer Batch Number: Chongqing Huapont Shengchem Pharmaceutical Co.LTD / TRER-20250105
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25G29-B03 / QO0021056

	Requirement	Result	Unit	Standard remark
Appearance	Yellow or light orange, crystalline powder	Conform		
Identification	A	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,00	%	
Unspecified impurities	<=0,2	<0,05	%	
Total impurities	<=1,0	0,18	%	
Loss on drying	<= 0,5	0,00	%	
Sulfated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	99,02	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		
TAMC	<=10 ³	<10 ²	cfu/g	
TYMC	<=10 ²	<10 ¹	cfu/g	

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 FSNE

Release:

12-9-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 12-1-2028

Conclusion: APPROVED

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