

Certificate of Analysis

Product name: Adrenalini tartras
Batch number / Weight: 25G03-B07-015034 / 1 g
Analyzed according to: Ph.Eur.11.8
Number of Analysis / Certificate no.: 25G03-B07 / QO0021428
Reference code / No.: V00610 / C38-250302

	Requirement	Result	Unit	Standard remark
Appearance	white or greyish-white, crystalline powder	Conform		
Identification	A, B, C	Conform		
Appearance of solution	<= ref. sus. II / <= BY5	Conform		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity A	<= 0,3	<0,05	%	
Impurity B	<= 0,2	<0,05	%	
Impurity C	<= 0,2	<0,05	%	
Impurity D	<= 0,1	0,00	%	
Impurity E	<= 0,1	0,00	%	
Unspecified impurities	<= 0,10	<0,05	%	
Total impurities	<= 0,6	0,00	%	
Loss on drying	<= 0,5	0,00	%	
Sulfated ash	<= 0,1	0,03	%	
Assay	98,5 - 101,0	99,00	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP

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 lab

Release:

16-9-2025
 Dominika Sottysik
 Qualified Person

Expiration: 29-2-2028

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.