

Certificate of Analysis

Productname: Adrenalini tartras
Number of analysis/Inspection Code: 1 / KEUR-186098B
Batchnumber: 20H10-F01-373893
Reference code / No.: 3863 / E80-18003
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Grey-)white, crystalline powder	Conform		
Identification A	-50 - -53,5	-52,2		2% <i>m/V</i> in HCl 0.5M; base
Identification B	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		Tartrate
Appearance of solution	<=ref. susp. II / <= BY5	Conform		5% <i>m/V</i>
Related substances	Conform	Conform	%	HPLC
Impurity A	<=0,3	0,2	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,6	0,2	%	
Loss on drying	<= 0,5	0,0	%	18 h vacuum
Sulphated ash	<= 0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Adrenaline hydrogen tartrate	98,5 - 101,0	98,9	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/05/20

Expiration: 04-2023

Conclusion: APPROVED

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