

Certificate of Analysis

Productname: Ergotamini tartras

Number of analysis/Inspection Code: 1 / KEUR-196163B

Batchnumber: 22F07-F02-383268

Reference code / No.: 1307 / IE2200293A

Analysed according to: PH.EUR10.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		Slightly hygroscopic!
Identification A		Conform		IR-spectrum
рН	4,0 - 5,5	5,1		0,25%
Related substances	Conform	Conform		HPLC
Impurity C	<= 0,4	0,2	%	
Impurity A	<= 0,2	0,0	%	
Impurity B	<= 0,2	0,2	%	
Unspecified impurities	<=0,10	0,07	%	
Total impurities	<=0,6	0,5	%	
Loss on drying	<=6,0	0,3	%	6 h 95°C;vacuum
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Ergotamine tartrate	98,0 - 101,0	99,3	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Manufacturer / Country : Curia Italy srl / IT

CEP :

Release:

Anthony Amoureus Qualified Person

11/02/22

Expiration: 30-04-27

Conclusion: APPROVED

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