

Certificate of Analysis

Productname: Dihydroergotamini mesilas
Number of analysis/Inspection Code: 1 / KEUR-185163B
Batchnumber: 19K07-F05-372653
Reference code / No.: 1201 / 72121000418
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		TLC
Appearance of solution	Clear / <=Y7 or BY7	Conform		
pH	4,4 - 5,4	5,2		0.1%m/V
Specific optical rotation	-47 - -42	-46		1%m/V anhydr. pyridine; dried
Related substances	Conform	Conform		HPLC
Impurity B	<=0,5	0,4	%	
Impurity E	<=0,5	<0,1	%	
Impurity C	<=0,3	<0,1	%	
Impurity A	<=0,15	0,01	%	
Impurity D	<=0,15	0,03	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,5	%	
Loss on drying	<=4,0	0,4	%	5 h 105 °C; vacuum
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Dihydroergotamine mesilate	98,0 - 101,0	99,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

08/20/20

Expiration: 11-2023

Conclusion: APPROVED

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