

## Certificate of Analysis

**Product name:** **Dihydroergotamini mesilas**

**Batch number / Weight:** **22E23-B06-223735 / 1 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22E23-B06 / INS-22-6682**

**Reference Code / No.:** **V01975 / 72121000422**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / $\leq Y7$ or BY7	Conform		
pH	4,4 - 5,4	5,04		
Specific optical rotation	-42 - -47	-43,4		
Related substances	Conform	Conform		
Impurity B	$\leq 0,5$	0,26	%	
Impurity E	$\leq 0,5$	$< 0,05$	%	
Impurity C	$\leq 0,3$	0,05	%	
Impurity A	$\leq 0,15$	$< 0,05$	%	
Impurity D	$\leq 0,15$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	0,063	%	
Total impurities	$\leq 1,0$	0,38	%	
Loss on drying	$\leq 4,0$	0,51	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dihydroergotamine mesila	98,0 - 101,0	99,14	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone	$\leq 5000$	$< 5000$	ppm	
Ethanol	$\leq 5000$	$< 5000$	ppm	
1,4-Dioxane	$\leq 380$	0,0	ppm	

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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 FAGRON PL lab

Release:  
Ewelina Gadzinowska  
Qualified Person

17-10-2022

Expiration: 30-05-2027

Conclusion: APPROVED

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