

Certificate of Analysis

Productname: Midazolami hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-197516B
Batchnumber: 21B03-F50-384607
Reference code / No.: 1068 / 050108
Analysed according to: DAC2022/2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chloride
Appearance of solution	Clear / <=Y6	Conform		1 g / 100 ml HCl 0.1M
pH	3,7 - 4,7	4,3		0.2%m/V
Related substances	Conform	Conform		HPLC
Impurity B	<=0,2	n.d.	%	
Impurity A	<=0,1	n.d.	%	
Impurity G	<=0,1	n.d.	%	
Any other impurity	<=0,10	0,10	%	
Sum of impurities	<=0,3	0,1	%	
Impurity C	<=0,1	Conform	%	TLC
Loss on drying	<=0,5	0,1	%	105 °C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Midazolam hydrochloride	98,5 - 101,5	99,5	%m/m	Dried
Endotoxins	<=0,25	Conform	EU/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs+Microb..

Manufacturer / Country : Cambrex Profarmaco Milano Srl / IT
CEP :

Release:
Anthony Amoureux
Qualified Person

05/03/23

Expiration: 31-12-25

Conclusion: APPROVED

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