

## Certificate of Analysis

**Productname:** Midazolami hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-196324B  
**Batchnumber:** 22C29-F03-383601  
**Reference code / No.:** 3581 / MIH/002/03/22  
**Analysed according to:** INTERN

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	4,5		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	<0,05	%	
Any other impurity	<=0,10	n.d.	%	
Sum of impurities	<=0,3	<0,05	%	
Impurity C	<=0,1	Conform	%	TLC
Loss on drying	<=0,5	0,5	%	105 °C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Midazolam hydrochloride	98,5 - 101,5	100,8	%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** : Ra Chem Pharma Ltd. / IN  
**CEP** :

Release:  
 Anthony Amoureux  
 Qualified Person

11/21/22

Expiration: 28-02-27

Conclusion: APPROVED

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