

Certificate of Analysis

Productname: Lorazepamum
Number of analysis/Inspection Code: 1 / KEUR-188083B
Batchnumber: 20K16-F01-375669
Reference code / No.: 4069 / 2002003P
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
Impurity B	<=0,1	0,1	%	
Impurity D	<=0,1	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Loss on drying	<=0,5	0,2	%	105 °C vacuo
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Lorazepam	98,5 - 102,0	100,8	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
Paul Hofman
Pharmacist - Qualified Person

01/08/21

Expiration: 08-2025

Conclusion: APPROVED

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