

Certificate of Analysis

Productname: Lorazepamum
Number of analysis/Inspection Code: 1 / KEUR-183721B
Batchnumber: 20D30-F01-371277
Reference code / No.: 4069 / 1902006P
Analysed according to: PH.EUR10.1

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	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Loss on drying	<=0,5	<0,1	%	105 °C vacuo
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Lorazepam	98,5 - 102,0	100,3	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

06/29/20

Expiration: 05-2024

Conclusion: APPROVED

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