

Certificate of Analysis

Productname: Prazepamum

Number of analysis/Inspection Code: 1 / KEUR-185612B

Batchnumber: 20G01-F01-373294

Reference code / No.: 1068 / 230106

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
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,1	%	
Loss on drying	<=0,5	0,1	%	105 °C
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Prazepam	99,0 - 101,0	100,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:

Paul Hofman

Pharmacist - Qualified Person

09/14/20

Expiration: 02-2024

Conclusion: APPROVED

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