

Certificate of Analysis

Productname: **Prazepamum**
Number of analysis/Inspection Code: 1 / KEUR-195949B
Batchnumber: **22H09-F01-383108**
Reference code / No.: 1992 / 202102260276
Analysed according to: **PH.EUR10.8**

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	<0,05	%	
Loss on drying	<=0,5	0,0	%	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 Prazepam	99,0 - 101,0	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Fabbrica Italiana Sintetici / IT
CEP :

Release:
Anthony Amoureux
Qualified Person

10/12/22

Expiration: 28-01-26

Conclusion: APPROVED

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