

Certificate of Analysis

Productname: Prazepamum
Number of analysis/Inspection Code: 1 / KEUR-198539B
Batchnumber: 22H09-F01-385502
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

05-01-24

Expiration: 28-01-26

Conclusion: APPROVED

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