

Certificate of Analysis

Productname: Diazepamum
Number of analysis/Inspection Code: 1 / KEUR-196146B
Batchnumber: 22F21-F01-383472
Reference code / No.: 4069 / 2101009P
Analysed according to: PH.EUR10.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Loss on drying	<=0,5	0,0	%	4 h 60°C; vacuum
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Diazepam	99,0 - 101,0	99,7	%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 : Centaur Pharm.PvtLtd API Divis / IN
CEP :

Release:
Anthony Amoureux
Qualified Person

11/02/22

Expiration: 31-10-26

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.