

Certificate of Analysis

Productname: Diazepamum
Number of analysis/Inspection Code: 1 / KEUR-181859B
Batchnumber: 19D17-B03-368752
Reference code / No.: 1992 / 201810090139
Analysed according to: PH.EUR 9.7

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	n.d.	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Loss on drying	<=0,5	<0,1	%	4 h 60°C; vacuum
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 Diazepam	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:
 Wai Lung Chung
 Pharmacist - Qualified Person

04/08/20

Expiration: 09-2023

Conclusion: APPROVED

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