

Certificate of Analysis

Productname: Chlordiazepoxidum
Number of analysis/Inspection Code: 1 / KEUR-198538B
Batchnumber: 23C21-F02-385520
Reference code / No.: 4069 / 2208201P
Analysed according to: PH.EUR11.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white or light yellow, crystalline powder	Conform Conform		
Identification	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	n.d.	%	
Impurity B	<=0,2	n.d.	%	
Impurity C	<=0,2	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<= 0,5	0,1	%	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 Chlordiazepoxide	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 : Centaur Pharm.PvtLtd API Divis / IN
CEP :

Release:
Anthony Amoureux
Qualified Person

05-01-24

Expiration: 31-01-27

Conclusion: APPROVED

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