

Certificate of Analysis

Productname: Oxazepamum
Number of analysis/Inspection Code: 1 / KEUR-197237B
Batchnumber: 22I08-F01-384354
Reference code / No.: 4069 / 2201503P
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	<=0,2	<0,05	%	
Impurity B	<=0,2	0,2	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,2	%	
Loss on drying	<= 0,5	0,0	%	105 °C vacuum
Sulphated ash	<= 0,1	<=0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Oxazepam	99,0 - 101,0	100,6	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Synergy Health Utrecht B.V.

Manufacturer / Country : Centaur Pharm.PvtLtd API Divis / IN
CEP :

Release:
 Anthony Amoureux
 Qualified Person

03/24/23

Expiration: 30-06-27

Conclusion: APPROVED

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