

## Certificate of Analysis

**Productname:** Bromazepamum  
**Number of analysis/Inspection Code:** 1 / KEUR-196321B  
**Batchnumber:** 21D09-F02-383156  
**Reference code / No.:** 4162 / 80201220020  
**Analysed according to:** PH.EUR10.4

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellowish) 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	<=0,2	0,0	%	4 h 80°C; <2.7 kPa
Sulphated ash	<=0,1	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Bromazepam	99,0 - 101,0	100,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Steris.

**Manufacturer / Country** : Lake Chemicals Pvt.(site) / IN  
**CEP** :

Release:  
 Anthony Amoureux  
 Qualified Person

11/21/22

Expiration: 30-11-25

Conclusion: APPROVED

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