

Certificate of Analysis

Productname: Butalbitalum
Number of analysis/Inspection Code: 1 / KEUR-196789B
Batchnumber: 22K22-F01-384048
Reference code / No.: 2711 / 2232X014
Analysed according to: USPNF 22/2

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Assay
Related substances	Conform	Conform	%	HPLC
Any individual unspecified impurity	<=0,10	0,01	%	
Total impurities	<=1	0	%	
Loss on drying	<=0,2	0,0	%	In vacuo
Sulphated ash	<=0,1	0,1	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Butalbital	98,0 - 102,0	100,2	%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 : Siegfried USA, LCC / US
CEP :

Release:
Anthony Amoureux
Qualified Person

01/23/23

Expiration: 23-09-27

Conclusion: APPROVED

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