

Certificate of Analysis

Productname: Butalbitalum
Number of analysis/Inspection Code: 1 / KEUR-179564B
Batchnumber: 18J17-B01-365578
Reference code / No.: 2711 / 1828X004
Analysed according to: USP 41

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	$\leq 0,10$	0,07	%	
Total impurities	≤ 1	0,2	%	
Loss on drying	$\leq 0,2$	$\leq 0,1$	%	In vacuo
Sulphated ash	$\leq 0,1$	$\leq 0,1$	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Butalbital	98,0 - 102,0	99,9	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/15/20

Expiration: 08-2023

Conclusion: APPROVED

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