

Certificate of Analysis

Productname: Codeinum Monohydricum
Number of analysis/Inspection Code: 1 / KEUR-198153B
Batchnumber: 23C01-F04-384828
Reference code / No.: 4177 / F.102.006/L
Analysed according to: PH.EUR11.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	155 - 159	157	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Loss on drying
Appearance of solution	Clear / colourless	Conform		
Specific optical rotation	-146 - -142	-145		Dried
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,1	%	
Impurity H	<=0,25	Not detected	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	0,1	%	
Impurity B	<=0,15	<0,05	%	
Impurity F	<=0,15	Not detected	%	
Impurity G	<=0,15	Not detected	%	
Impurity I	<=0,15	Not detected	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	0,1	%	
Loss on drying	4,0 - 6,0	4,6	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Codeine	99,0 - 101,0	100,4	%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 : Alcaliber S.A.U (site) / ES
CEP : R1-CEP2013-046-Rev00

Release:
Anthony Amoureux
Qualified Person

09/19/23

Expiration: 31-10-27

Conclusion: APPROVED

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