

Certificate of Analysis

Productname:	Codeinum Monohydricum
Number of analysis/Inspection Code:	1 / KEUR-195658B
Batchnumber:	22A31-F01-382406
Reference code / No.:	4177 / F102.002/K
Analysed according to:	PH.EUR10.7

Appearance(Almost) white, crystalline powder or colourless crystalsConformConformIdentification A155 - 159157°CMelting pointIdentification BConformConformIR-spectrumIdentification EConformConformIR-spectrumAppearance of solutionClear / colourlessConformIDSpecific optical rotation-146 - 142-145DriedRelated substancesConformConformHPLCImpurity A<=1,00,1%Impurity G<=0,20,1%Impurity C<=0,2n.d.%Impurity D<=0,20,1%Impurity F<=0,10,1%Impurity G<=0,150,05%Impurity G<=0,150,05%Impurity G<=0,10n.d.%Impurity I<=0,100,0%Impurity G<=0,100,2%Inspecified impurities<=0,10,0%Subpated ash<=0,10,0%Kasay Codeine<=0,10,0%Netalic residuesCHMP/ICH/353369/2013ConformData producerResiduel solventsCHMP/ICH/82260/206ConformData producerResiduel solventsMotortaniation with TSE/BSE-risk materialsConformData producerCEPCEP availableConformData producerData producer	Tests	Requirement	Result	Unit	Standard remark
Identification A155 - 159167*CMelting pointIdentification BConformConformIR-spectrumIdentification EConformConformLoss on dryingAppearance of solutionClear / colourlessConformLoss on dryingSpecific optical rotation-146142-145DriedRelated substancesConformConformMPLCImpurity A<=1,0					
Identification BConformConformRespert mIdentification EConformConformLoss on dryingAppearance of solutionClear / colourlessConformConformSpecific optical rotation146 - 142-145DriedRelated substancesConformConformHPLCImpurity A<=1,0	Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification EConformConformLeas on dryingAppearance of solutionClear / colourlessConformConformSpecific optical rotation-146 - 142-145DriedRelated substancesConformConformHPLCImpurity A<=1.0	Identification A	155 - 159	157	°C	Melting point
Appearace of solutionClear / colourlessConformDriedSpecific optical rotation-146 - 142-145DriedRelated substancesConformConformHPLCImpurity A<=1,0	Identification B	Conform	Conform		IR-spectrum
Specific optical rotation.146142 145 DriedRelated substancesConform $HPLC$ Impurity A<=1,0	Identification E	Conform	Conform		Loss on drying
Related substances Conform Conform HPLC Impurity A <=1,0	Appearance of solution	Clear / colourless	Conform		
Impurity A <=1,0 0,1 % Impurity H <=0,25	Specific optical rotation	-146142	-145		Dried
Impurity H <-0,25 <-0,05 %- Impurity C <-0,2	Related substances	Conform	Conform		HPLC
Impurity C <=0.2 n.d. % Impurity D <=0.2	Impurity A	<=1,0	0,1	%	
Impurity D <=0,2 n.d. % Impurity E <=0,2	Impurity H	<=0,25	<0,05	%	
Impurity E<=0,20,1%Impurity B<=0,15	Impurity C	<=0,2	n.d.	%	
Inpurity B<=0,15<0,05%Impurity F<=0,15	Impurity D	<=0,2	n.d.	%	
Impurity F<=0,15<0,05%Impurity G<=0,15	Impurity E	<=0,2	0,1	%	
Inductive Impurity G<=0,15n.d.%Impurity I<=0,15	Impurity B	<=0,15	<0,05	%	
Impurity I<=0,15n.d.%Unspecified impurities<=0,10	Impurity F	<=0,15	<0,05	%	
Unspecified impurities<=0,10n.d.%Total impurities<=1,5	Impurity G	<=0,15	n.d.	%	
Total impurities<=1,50,2%Loss on drying4,0 - 6,04,8%105°CSulphated ash<=0,1	Impurity I	<=0,15	n.d.	%	
Loss on drying4,0 - 6,04,8%105°CSulphated ash<=0,1	Unspecified impurities	<=0,10	n.d.	%	
Sulphated ash<=0,10,0%Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformAssay Codeine99,0 - 101,0100,3%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Total impurities	<=1,5	0,2	%	
Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformConformAssay Codeine99,0 - 101,0100,3%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Loss on drying	4,0 - 6,0	4,8	%	105°C
Residual solvents CHMP/ICH/82260/2006 Conform Assay Codeine 99,0 - 101,0 100,3 %m/m Dried TSE/BSE-statement: No contamination with TSE/BSE-risk materials Conform Data producer	Sulphated ash	<=0,1	0,0	%	
Assay Codeine99,0 - 101,0100,3%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement: No contamination with TSE/BSE-risk materials Conform Data producer	Residual solvents	CHMP/ICH/82260/2006	Conform		
	Assay Codeine	99,0 - 101,0	100,3	%m/m	Dried
CEP CEP available Conform Data producer	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 Proxylabs.

Release: Anthony Amoureus Qualified Person

09/09/22

Expiration: 07-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.