

## Certificate of Analysis

**Productname:** Codeini phosphas hemihydr.(90)  
**Number of analysis/Inspection Code:** 1 / KEUR-180174B  
**Batchnumber:** 19A30-B06-367121  
**Reference code / No.:** 3960 / 5100618 D  
**Analysed according to:** PH.EUR9.6+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder or small colorless crystals	Conform		
Particle size	97% < 90 µm	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification E	1,5 - 3,0	2,3	%	Loss on drying
Identification F	Conform	Conform		Phosphate
pH	4,0 - 5,0	4,4		4%m/V
Specific optical rotation	-102 - -98	-101		2%m/V; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,5	%	
Impurity B	<=0,15	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	n.d.	%	
Impurity E	<=0,2	0,1	%	
Impurity F	<=0,15	n.d.	%	
Impurity G	<=0,15	<0,05	%	
Impurity H	<=0,25	n.d.	%	
Impurity I	<=0,15	0,08	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	0,7	%	
Sulphates	<=0,1	<0,1	%	
Loss on drying	1,5 - 3,0	2,5	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Codeini phosph. hemih.	99,0 - 101,0	99,6	%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

02/12/20

Expiration: 05-2023

Conclusion: APPROVED

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