Fagron

Certificate of Analysis

Productname:	**Codeini phosphas hemihydr.(90)**
Number of analysis/Inspection Code:	1 / KEUR-198443B
Batchnumber:	**23J04-F05-385498**
Reference code / No.:	3960 / 5170923
Analysed according to:	**PHEUR11.2+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder or small colorless crystals	Conform		
Particle size	97% < 90 µm	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	1,5 - 3,0	2,2		Loss on drying
Identification E	Conform	Conform		Phosphate
pH	4,0 - 5,0	4,5		4%m/V
Specific optical rotation	-102 - -98	-101		2%m/V; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,2	%	
Impurity H	<=0,25	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	<0,05	%	
Impurity B	<=0,15	<0,05	%	
Impurity F	<=0,15	<0,05	%	
Impurity G	<=0,15	<0,05	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=1,5	0,3	%	
Sulphates	<=0,1	<0,1	%	
Loss on drying	1,5 - 3,0	2,2	%	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	99,9	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country	:	Saneca Pharmaceuticals a.s. / SK
CEP	:	

Release:
Anthony Amoureus
Qualified Person

11/23/23

Expiration: 31-08-28

Conclusion: APPROVED

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