

**CODEINI PHOSPHAS HEMIHYDRICUS 25 G**

Lot No.: 23D19-AP23203

Autorisation :	1890IR05810	Date Of Analysis :	17/04/2023
Analytical Reference :	Ph. Eur. [01/2021:0074]	Production Number :	191223-5141022
CNK :	4178-844	Expiry Date :	09/2027

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or small, colourless crystals.	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with Ph. Eur. reference spectrum of codeine.	Complies
Identification D	1.5% to 3.0%	1.6%
Identification E	Solution S gives reaction (a) of phosphates.	Complies
TESTS	SPECIFICATION	RESULT
pH	4.0 to 5.0 for solution S.	4.4
Specific optical rotation	- 102 to - 98 (dried substance)	- 102
Related substances		
Impurity A	≤ 1.0%	0.5%
Impurity H	≤ 0.25%	< 0.05%
Impurity C	≤ 0.2%	< 0.1%
Impurity D	≤ 0.2%	< 0.1%
Impurity E	≤ 0.2%	< 0.1%
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%	< 0.05%
Total	≤ 1.5%	0.5%
Sulfates	≤ 0.1%	< 0.1%
Loss on drying	1.5% to 3.0%	1.6%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	99.3%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: