

Certificate of Analysis

Productname: Ethylmorphini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-198716B
Batchnumber: 23D13-F03-385869
Reference code / No.: 2021 / AVL1182
Analysed according to: PH.EUR11.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		
Appearance of solution	Clear <=BY6	Conform		
Acidity or alkalinity	Yellow	Conform		
Specific optical rotation	-102 - -105	-104		Anhydrous
Related substances	Conform	Conform		
Impurity A	<=0,2	Not detected	%	
Impurity B	<=0,2	0,1	%	
Impurity C	<=0,5	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Any other impurity	<=0,1	0,1	%	
Total impurities other than C	<=0,5	0,1	%	
Water (Karl Fischer)	8,0 - 10,0	9,5	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Ethylmorphine hydrochloride	99,0 - 101,0	100,3	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Alkaloida Chemical Company ZRT / HU
CEP :

Release:
Anthony Amoureux
Qualified Person

14-03-24

Expiration: 31-10-26

Conclusion: APPROVED

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