

Certificate of Analysis

Productname: Morphini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-184563B
Batchnumber: 20E28-F06-372127
Reference code / No.: 4177 / 2/20
Analysed according to: PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless, silky needles or cubic masses	Conform Conform Conform		
Particle size	97% < 125 µm	Conform		Microscopy
Identification A	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear / <=Y6 or BY6	Conform		2%m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-110 - -115	-114		2%m/V; dried
Related substances	Conform	Conform		HPLC
Impurity B	<=0,4	<0,05	%	
Impurity C	<=0,2	n.d.	%	
Impurity E	<=0,2	<0,05	%	
Any other impurity	<=0,2	0,1	%	
Total impurities	<=1,0	0,1	%	
Water (Karl Fischer)	12,5 - 15,5	13,2	%	
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Morphine hydrochloride	98,0 - 102,0	99,9	%m/m	Anhydrous
Total aerobic microbial count (TAMC)	<=10	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=1	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs+Microb..

Release:

Paul Hofman

Pharmacist - Qualified Person

08/04/20

Expiration: 04-2025

Conclusion: APPROVED

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