Fagron

Certificate of Analysis

Productname: **Hydromorphoni hydrochloridum**

Number of analysis/Inspection Code: 1 / KEUR-198431B

Batchnumber: **22D28-F03-385240**

Reference code / No.: 3960 / 5010321

Analysed according to: **PH.EUR10.7**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost)white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Chloride
Appearance of solution	Clear / <=BY5	Conform		5%m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-140 - -136	-138		5%m/V; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,3	0,1	%	
Impurity B	<=0,2	n.d.	%	
Impurity C	<=0,2	n.d.	%	
Impurity D	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,1	%	
Loss on drying	<=0,5	0,2	%	105°C
Sulphated ash	<=0,1	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Hydromorphone hydrochloride	99,0 - 101,0	99,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	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: 28-02-26

Conclusion: APPROVED

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