

## Certificate of Analysis

**Productname:** Haloperidolum  
**Number of analysis/Inspection Code:** 1 / KEUR-179525B  
**Batchnumber:** 17E15-B01-365163  
**Reference code / No.:** 4106 / 03538400516  
**Analysed according to:** PH.EUR 9.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	150 - 153	151	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear <=Y7	Conform		1% <i>m/V</i> lactic acid 1% <i>V/V</i>
Related substances	Conform	Conform		HPLC
Impurity B	<=0,3	0,1	%	
Impurity D	<=0,5	<0,05	%	
Impurity G	<=0,15	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=1,0	<1,0	%	
Loss on drying	<=0,5	0,2	%	105°C
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 Haloperidol	99,0 - 101,0	100,7	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:  
 dr. M.J. Vincenten - van Maanen  
 Pharmacist - Qualified Person

01/13/20

Expiration: 11-2021

Conclusion: APPROVED

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