Certificate of Analysis

Product name: **Haloperidolum**

Batch number / Weight: **22C03-B02-230911 / 300 MG**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **22C03-B02 / INS-22-3457**

Reference Code / No.: **V01877 / 03538400821**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform	%	
Appearance of solution	Clear <=Y7	Conform		
Related substances	Conform	Conform		
Impurity B	<=0,3	0,13	%	
Impurity D	<=0,5	<0,05	%	
Impurity G	<=0,15	0,00	%	
Impurity H	<=0,15	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,13	%	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Haloperidol	99,0 - 101,0	99,66	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents		Conform		
Acetone	<5000 ppm	<5000	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

22-06-2023

Expiration: 31-05-2026

Conclusion: APPROVED

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