

Certificate of Analysis

Product name: Haloperidolum
Batch number / Weight: 22C03-B02-230298 / 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	

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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 Soltysik
Qualified Person

22-06-2023

Expiration: 31-05-2026

Conclusion: APPROVED

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl