

Certificate of Analysis

Product name: Haloperidolum
Batch number / Weight: 22A26-B02-217515 / 1 G
Analysed according to: Ph. Eur.

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	0,10	%	
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	0,10	%	
Loss on drying	≤0,5	0,01	%	
Sulphated ash	≤0,1	0,04	%	
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				
Acetone	<5000 ppm	<5000	ppm	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-04-2022

Expiration: 31-05-2025

Conclusion: APPROVED

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