

Certificate of Analysis

Product name: **Dithranolum**

Batch number / Weight: **20G27-B01-202105 / 5 G**

Analysed according to: **Ph. Eur.04/2018:0049**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow (-brown), crystalline powder	Conform		
Identification A	178 - 182	181,8	°C	
Identification B	Conform	Conform		
Related substances A	Conforme	Conform		
Impurity A	<=1	<0,05	%	
Impurity B	<=1	0,14	%	
Impurity C	<=1	0,72	%	
Related substances B	Conform	Conform	%	
Impurity D	<=2,5	<0,1	%	
Related substances A+B	<=3,0	0,9	%	
Chlorides	<=100	Conform	ppm	
Loss on drying	<= 0,5	0,04	%	
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0 (dried substance)	100,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

24-08-2020

Expiration: 29-06-2025

Conclusion: APPROVED

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