

Certificate of Analysis

Product name: **Dithranolum**
Batch number / Weight: **22F11-B02-219478 / 5 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22F11-B02 / INS-22-5243**
Reference Code / No.: **V01094 / OP-DNL-C1-001/22**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow (-brown), crystalline powder	Conform		
Identification A	178 - 182	181,4	°C	
Identification B	Conform	Conform		
Related substances A	Conforme	Conform		
Impurity A	<=1	<0,05	%	
Impurity B	<=1	0,86	%	
Impurity C	<=1	<0,05	%	
Related substances B	Conform	Conform		
Impurity D	<=2,5	0,18	%	
Related substances A+B	<=3,0	1,04	%	
Chlorides	<=100	Conform	ppm	
Loss on drying	<= 0,5	0,03	%	
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	98,5 - 101,0 (dried substance)	100,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
N,N-dimethylformamide	<=880	0,0	ppm	
Isopropanol	<=5000	0,0	ppm	
Methanol	<=3000	<26	ppm	
Acetic acid	<=5000	0,0	ppm	
Toluene	<=890	390,4	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:
Ewelina Gadzinowska
Qualified Person

25-08-2022

Expiration: 04-03-2027

Conclusion: APPROVED

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