

Certificate of Analysis

Productname: Metronidazolium micronisatum
Number of analysis/Inspection Code: 1 / KEUR-180795B
Batchnumber: 19G02-B04-367359
Reference code / No.: 1305 / 603041926
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish, crystalline powder	Conform		
Particle size	>90% < 30 µm	100		Data producer
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	<= ref. susp.II / <= GY6	Conform		5% <i>m/V</i> HCl 1M
Related substances	Conform	Conform		HPLC
Any impurity	<=0,1	<0,01	%	
Total impurities	<=0,2	0,0	%	
Sulphated ash	<= 0,1	0,0	%	
Loss on drying	<=0,5	0,1	%	3H 105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Metronidazole	99,0 - 101,0	99,6	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/27/20

Expiration: 04-2022

Conclusion: APPROVED

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