



Certificate of Analysis

Productname: Metronidazolium apyrogen
Number of analysis/Inspection Code: 1 / KEUR-106452B
Batchnumber: 13G10-B03-291191 ✓
Reference code / No.: 1305 / 201041327
Analysed according to: PH.EUR7.8+

FARMADENT d.o.o.
Minarikova ul.6
2000 Maribor
Projek: FUJS DRAGO
Isc: [Signature]
Datum prejete: 12.5.14.
Pregledal: MAROLT Robert, mag. farm., spec.
Datum pregleda: 16.5.14.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish, crystalline powder	Conform		
Identification	Conform	Conform		IR-spectrum
Appearance of solution	<= ref. susp.II / <= GY6	Conform		5% <i>m</i> /V HCl 1M
Related substances	Conform	Conform		HPLC
Any impurity	<=0,1	n.d.	%	
Total impurities	<=0,2	n.d.	%	
Heavy metals	<= 20	Conform	ppm	
Sulphated ash	<= 0,1	Conform	%	
Loss on drying	<=0,5	<0,1	%	3 h 105 °C
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Metronidazole	99,0 - 101,0	99,8	% <i>m</i> /m	Dried
Endotoxins	<= 0,35	Conform	IU / mg	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Proxylabs+Microb..

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

04/01/14

Expiration: 07-2016 ✓

Conclusion: APPROVED

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