



Certificate of Analysis

FARMADENT d.o.o.	
Minarikova ul. 6	
2000 Maribor	
Prejel: FUJB DRAGO	
Z.A. : <i>[Signature]</i>	
Datum prejema: <i>1.4.14</i>	
Pregledal: MAROLT Robert, mag. farm. spec.	
Datum pregleda: <i>2.4.2014</i>	

Productname: **Metronidazolom apyrogen**
Number of analysis/Inspection Code: 1 / KEUR-96253B
Batchnumber: **12G20-B02-281756**
Reference code / No.: 2187 / MTZ/2070552
Analysed according to: **PH.EUR7.5+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish, crystalline powder	Conform		
Identification C	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	0,03	%	
Total impurities	<=0,2	0,05	%	
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	100,0	% <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

03-06-13

Expiration: 07-2017

Conclusion: APPROVED

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