



Certificate of Analysis

Productname: **Ethinylestradiolum**
Number of analysis/Inspection Code: 1 / KEUR-83385B
Batchnumber: **11D12-B06-269623** ✓
Reference code / No.: 2456 / 80303890
Analysed according to: **PH.EUR 7.1**

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJIS DRAGO <i>Zeljko Jozicnik</i> Datum prejema: <i>6.11.2012</i> Pregledal: MATOLT Robert, mag. farm., spec. <i>Robert Matolt</i> Datum pregleda: <i>7.11.2012</i>

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		TLC
Related substances	Conform	Conform		HPLC
Impurity B	<=0,5	0,3	%	
Impurity H	<=0,2	n.d.	%	
Impurity I	<=0,2	0,1	%	
Impurity K	<=0,2	0,1	%	
Impurity C	<=0,15	n.d.	%	
Impurity F	<=0,15	n.d.	%	
Unspecified impurities	<=0,10	0,07	%	
Total impurities	<=0,8	0,5	%	
Loss on drying	<=1,0	<0,1	%	3 h 105 °C
Assay	97,0 - 102,0	98,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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

03-05-12

Expiration: 04-2016 ✓

Conclusion: APPROVED

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