



Certificate of Analysis

Productname: Ethinylestradiolum
Number of analysis/Inspection Code: 1 / KEUR-73174B
Batchnumber: 11D12-B06 ✓
Reference code / No.: 2456 / 80303890
Analysed according to: PH.EUR 7.1

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO Za: <i>[Signature]</i> Datum prejema: 4.10.2011 Prejedat: MAROLT Rober / mag. farm. spec. Datum pregleda: 8.10.2011

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	$\leq 0,5$	0,3	%	
Impurity H	$\leq 0,2$	n.d.	%	
Impurity I	$\leq 0,2$	0,1	%	
Impurity K	$\leq 0,2$	0,1	%	
Impurity C	$\leq 0,15$	n.d.	%	
Impurity F	$\leq 0,15$	n.d.	%	
Unspecified impurities	$\leq 0,10$	0,07	%	
Total impurities	$\leq 0,8$	0,5	%	
Loss on drying	$\leq 1,0$	$< 0,1$	%	3 h 105 °C
Assay Ethinylestradiol	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

29-04-11

Expiration: 04-2016 ✓

Conclusion: APPROVED

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