

## Certificate of Analysis

**Productname:** Ethinylestradiolum micro  
**Number of analysis/Inspection Code:** 1 / KEUR-195342B  
**Batchnumber:** 22A18-F02-382528  
**Reference code / No.:** 3972 / UN8059P  
**Analysed according to:** PHEUR10.7+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Particle size		Conform		Microscopy
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	<0,05	%	
Impurity I	<=0,2	0,1	%	
Impurity K	<=0,2	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,8	0,3	%	
Loss on drying	<=1,0	0,1	%	3H 105°C
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Ethinylestradiol	97,5 - 102,0	99,4	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
 Anthony Amoureux  
 Qualified Person

08/10/22

Expiration: 05-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.