



CERTIFICATE OF ANALYSIS

Oss, 17-May-2013
The Netherlands

Product : Etonogestrel micronised
Quality : Organon
Bulk batch number : L00036031
Date of release : 19-Apr-2013
Manufacturing date : 18-Mar-2013
To be used before : Feb-2018

Requirements	Specifications	Results
APPEARANCE	CRYSTALLINE POWDER	COMPLIES
COLOUR	WHITE TO PRACTICALLY WHITE	COMPLIES
IR-SPECTRUM	IDENTICAL WITH REFERENCE SPECTRUM	COMPLIES
CHROMATOGRAM	IDENTICAL WITH STANDARD	COMPLIES
PARTICLE SIZE:		
<= 30 MCM	>= 90 % N/N	100
> 100 MCM	<= 0.1 % N/N	0.0
MELTING POINT AVG	196.5 <= x <= 199.5 DEGREES C	198.2
LOSS ON DRYING AVG	<= 0.5 %	< 0.05
SPECIFIC OPTICAL ROTATION AVG AS DRD.SUB	+84 <= x <= +91 DEGREES	+87
SULPHATED ASH	<= 0.1 %	<= 0.1
POLYMORPHY:		
CRYSTAL MODIFICATION I	>= 90 %	>= 90
RELATED SUBSTANCES:		
ORG 10982	<= 0.1 %	< 0.05
ORG 32084	<= 0.1 %	< 0.05
ORG 2761	<= 0.4 %	< 0.05
ORG 33669	<= 0.5 %	< 0.1
ORG 31977	<= 0.5 %	< 0.05
UNSPECIFIED EACH	<= 0.10 %	< 0.05
TOTAL RELATED SUBSTANCES	<= 1.5 %	< 0.1
LIMIT TEST ON HEAVY METALS	<= 20 MG/KG	<= 20



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RESIDUAL SOLVENTS:		
TOLUENE	<= 500 PPM	< 100
HEPTANE	<= 500 PPM	< 100
ETHANOL	<= 500 PPM	< 100
METHANOL	<= 500 PPM	< 100
PYRIDINE	<= 200 PPM	< 100
OTHER RESIDUAL SOLVENTS	<= 500 PPM	< 100
TOTAL RESIDUAL SOLVENTS	<= 2000 PPM	<= 2000
VISIBLE IMPURITIES	FREE FROM VISIBLE IMPURITIES	COMPLIES
AEROBIC VIABLE COUNT	<= 100 CFU/GRAM	< 10
ETONOGESTREL AVG AS DRD.SUB	97.5 <= x <= 101.5 %	100.4

Tested according to the methods of article identification COP-3273

FOR REGISTRATIONAL PURPOSE ONLY

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labeling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

NV Organon

Drs. P. Smit

Responsible Pharmacist/Qualified Person