



# 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<br>WHITE        | COMPLIES |
| IR-SPECTRUM                                    | IDENTICAL WITH<br>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<br>DEGREES C     | 198.2    |
| LOSS ON DRYING AVG                             | <= 0.5 %                             | < 0.05   |
| SPECIFIC OPTICAL<br>ROTATION AVG AS<br>DRD.SUB | +84 <= x <= +91 DEGREES              | +87      |
| SULPHATED ASH                                  | <= 0.1 %                             | <= 0.1   |
| POLYMORPHY:                                    |                                      |          |
| CRYSTAL<br>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<br>SUBSTANCES                    | <= 1.5 %                             | < 0.1    |
| LIMIT TEST ON<br>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