

MOEHS CATALANA, S.L.

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## CERTIFICATE OF ANALYSIS

Code: 15620

Product : NIFEDIPINE Ph. Eur. 7 / USP 36

Batch Nr: 226/3

Manufacture: 09/2013

Re-test Date: 09/2018

Client : FAGRON SERVICES B.V.

Shipment (Kg): 3.00

Packs: 1

| TESTS                          | SPECIFICATIONS            | RESULTS        |
|--------------------------------|---------------------------|----------------|
| CHARACTERS                     | Conforms to Ph.Eur. & USP | Conforms       |
| IDENTIFICATION                 |                           |                |
| .IR Spectrum                   | Conforms to St            | Conforms       |
| .UV spectrum                   | Conforms to St            | Conforms       |
| .HPLC                          | Conforms                  | Conforms       |
| TESTS                          |                           |                |
| Melting range                  | 171°C to 175°C            | 171.5-172.6 °C |
| Impurity D & other basic impur | Maximum 0.14 p.cent       | 0.03 p.cent    |
| Perchloric acid 0.1N titration | Maximum 0.12 ml/g         | 0.03 ml/g      |
| Related substances (HPLC)      |                           |                |
| .Impurity A (Nitrophenyl An)   | Maximum 0.1 p.cent        | < 0.01 p.cent  |
| .Impurity B (Nitrosophenyl An) | Maximum 0.1 p.cent        | < 0.01 p.cent  |
| .Impurity C                    | Maximum 0.1 p.cent        | < 0.01 p.cent  |
| .Any other impurity (biggest)  | Maximum 0.10 p.cent       | 0.08 p.cent    |
| .Total impurities              | Maximum 0.3 p.cent        | 0.15 p.cent    |
| Heavy metals                   | Maximum 10 ppm (0.001%)   | < 10 ppm       |
| Chloride                       | Max 0.02 p.cent (200 ppm) | < 0.02 p.cent  |
| Sulfate                        | Max 0.05 p.cent (500 ppm) | < 0.05 p.cent  |
| Loss on drying                 | Maximum 0.5 p.cent        | < 0.01 p.cent  |
| Sulfated ash                   | Maximum 0.1 p.cent        | 0.05 p.cent    |
| ASSAY                          |                           |                |
| .Redox (on dried substance)    | 98.0 to 102.0 p.cent      | 99.9 p.cent    |
| .HPLC (on dried subs)          | 98.0 to 102.0 p.cent      | 99.9 p.cent    |
| ADDITIONAL TESTS               |                           |                |
| Residual solvents (GC)         | Ph.Eur. 5.4 & USP 467     | Conforms       |
| .Methylene chloride            | Maximum 100 ppm (0.01%)   | < 20 ppm       |
| .Toluene                       | Maximum 890 ppm           | 187 ppm        |

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site, in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7A.

FAGRON IBÉRICA, S.A.U  
Corresponde al lote de Fagron:

13L04-006

Director Técnico

Released by QA on 01/10/2013  
CoA issued on 26/11/2013  
Signed by Quality Control

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