

CERTIFICATE OF ANALYSIS

Code: 15620

Product : NIFEDIPINE Ph. Eur. 8 / USP 36

Batch Nr: 234/3

Manufacture: 02/2014

Re-test Date: 02/2019

Client : FAGRON SERVICES B.V.

Shipment (Kg): 3.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS IDENTIFICATION .IR Spectrum .UPLC TESTS Impurity D & other basic impur Perchloric acid 0.1N titration RELATED SUBSTANCES (UPLC) .Impurity A (Nitrophenyl An) .Impurity B (Nitrosophenyl An) .Impurity C .Any unspecified impurity .Total impurities Heavy metals Chloride Sulfate Loss on drying Sulfated ash ASSAY .Redox (on dried substance) .UPLC (on dried substance) ADDITIONAL TESTS Residual solvents (GC) .Methylene chloride .Toluene	Conforms to Ph.Eur. & USP Conforms to St Conforms Maximum 0.14 p.cent Maximum 0.12 ml/g Maximum 0.1 p.cent Maximum 0.1 p.cent Maximum 0.1 p.cent Maximum 0.10 p.cent Maximum 0.3 p.cent Maximum 10 ppm (0.001%) Max 0.02 p.cent (200 ppm) Max 0.05 p.cent (500 ppm) Maximum 0.5 p.cent Maximum 0.1 p.cent 98.0 to 102.0 p.cent 98.0 to 102.0 p.cent Ph.Eur. 5.4 & USP 467 Maximum 100 ppm (0.01%) Maximum 890 ppm	Conforms Conforms Conforms 0.01 p.cent 0.01 ml/g < 0.01 p.cent < 0.01 p.cent < 0.01 p.cent < 0.01 p.cent < 0.01 p.cent < 0.01 p.cent < 10 ppm < 0.02 p.cent < 0.05 p.cent < 0.01 p.cent 0.01 p.cent 100.8 p.cent 100.7 p.cent Conforms < 20 ppm 190 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 IBERICA, S.A.U.
Corresponde al lote de Fagron:

14024-B02

Director Técnico

Released by QA on 14/03/2014
CoA issued on 15/07/2014
Signed by Quality Control

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