

MOEHS CATALANA, S.L.

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Nifedipinum**CERTIFICATE OF ANALYSIS**

Code: 15620

Product : NIFEDIPINE Ph. Eur. 8 / USP 36Batch Nr : 234/3Manufacture : 02/2014Re-test Date : 02/2019Client : FAGRON SERVICES B.V.Shipment (Kg) : 3.00Packs : 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	Conforms to Ph.Eur. & USP	Conforms
IDENTIFICATION		
.IR Spectrum	Conforms to St	Conforms
.UPLC	Conforms	Conforms
TESTS		
Impurity D & other basic impur	Maximum 0.14 p.cent	0.01 p.cent
Perchloric acid 0.1N titration	Maximum 0.12 ml/g	0.01 ml/g
RELATED SUBSTANCES (UPLC)		
.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 unspecified impurity	Maximum 0.10 p.cent	< 0.01 p.cent
.Total impurities	Maximum 0.3 p.cent	< 0.01 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	0.01 p.cent
ASSAY		
.Redox (on dried substance)	98.0 to 102.0 p.cent	100.8 p.cent
.UPLC (on dried substance)	98.0 to 102.0 p.cent	100.7 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	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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