

NIFEDIPINA (EUR. PH.)			
PRODUCT CODE: 1331		CAS Nº: 21829-25-4	ANALYSIS Nº: 355/25
MANUFACTURER BATCH:	NFDG250004	CERTIFICATE ID:	49.097
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/03/2025
METAPH BATCH:	0091125	RETEST DATE:	28/02/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow, crystalline powder	Yellow crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol	Complies (*)
Identification B	Complies	Complies
Impurity D and other basic impurities	=< 0.14 %	< 0.14 %
Related substances		
Impurity A	=< 0.1 %	0.01 %
Impurity B	=< 0.1 %	0.03 %
Any other impurity	=< 0.1 %	< 0.05 % (#)
Total impurities	=< 0.3 %	0.06 %
Loss on drying	=< 0.5 %	0.08 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.0 - 102.0 %	99.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

RT (6.30 min) = 0.01 %

RT (29.97 min) = 0.01 %

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Nifedipine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Release date: 26/11/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40001226
SHILPA PHARMA LIFESCIENCES LIMITED
Unit-2: Plot No: 33, 33a & 40-47
Raichur Industrial Growth Center
584 134 Chicksugur

Original certificate available upon request

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STORAGE

Keep the containers in a well-ventilated and dry place.

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