METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

NIFEDIPINA (EUR. PH.)

PRODUCT CODE: 1331	CAS Nº: 21829-25-4	ANALYSIS Nº: 191/24	
MANUFACTURER BATCH:	23011NFD1RA	CERTIFICATE ID:	42.995
SUPPLIER BATCH:	----	MANUFACTURING DATE:	31/05/2023
METAPH BATCH:	0140724	EXPIRY DATE:	30/04/2028

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 %	Not Detected
Impurity B	=< 0.1 %	0.09 %
Any other impurity	=< 0.1 %	< 0.05 %
Total impurities	=< 0.3 %	0.09 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	98.0 - 102.0 %	100.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) 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.

STORAGE

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

Analysis date: 03/09/2024
Signature: Cristina Borrell Olea (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000356