METAPHARMACEUTICAL

TECHNICAL DATA SHEET

1331-TDS-ENG-2025

NIFEDIPINA (EUR. PH.)		
DESCRIPTION DCI: nifedipine	DESCRIPTION DOE: NIFEDIPINO	
CAS Nº: 21829-25-4	EC Nº: 244-598-3	AEMPS CODE: 3253A
MOL. WEIGHT: 346,34	MOL. FORMULA: C17H18N2O6	ARTICLE CODE: 1331

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869