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TECHNICAL DATA SHEET

46433074-TDS-ENG-2024

TELMISARTAN (EUR. PH.)		
DESCRIPTION DCI: TELMISARTAN	DESCRIPTION DOE: TELMISARTAN	
CAS Nº: 144701-48-4	EC Nº: 620-494-7	AEMPS CODE: 1099A
MOL. WEIGHT: 514,62	MOL. FORMULA: C33H30N4O2	ARTICLE CODE: 46433074

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, crystalline powder
Solubility	Practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. It dissolves in a 40 g/L solution of sodium hydroxide
Identification	Complies
Appearance of solution	The solution is not more intensely coloured than reference solution Y4
Related substances	
Impurity C	=< 0,2 %
Impurity D	=< 0,2 %
Impurity A	=< 0,15 %
Impurity B	=< 0,15 %
Unspecified impurities	=< 0,10 %
Total impurities	=< 1,0 %
Loss on drying	=< 0,5 %
Sulfated ash	=< 0,1 %
Assay	99,0 - 101,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

It shows polymorphism.

Telmisartan is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.