

**TELMISARTAN (EUR. PH.)**

PRODUCT CODE: 46433074	CAS Nº: 144701-48-4	ANALYSIS Nº: 295/24
MANUFACTURER BATCH: TL019J24	CERTIFICATE ID: 44.221	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/10/2024	
METAPH BATCH: 0201124	EXPIRY DATE: 30/09/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellowish, crystalline powder	White 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	Complies (*)
Identification	Complies	Complies
Appearance of solution	Not more intensely coloured than reference solution Y4	Complies
Related substances		
Impurity C	=< 0.2 %	Not Detected
Impurity D	=< 0.2 %	< 0.05 %
Impurity A	=< 0.15 %	< 0.05 %
Impurity B	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	< 0.05 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 101.0 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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".

(*) 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

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

Analysis date: 23/01/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001498
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