

TECHNICAL DATA SHEET

1397-TDS-ENG-2026

PENTOXIFILINA (EUR. PH.)		
DESCRIPTION DCI: pentoxifylline		DESCRIPTION DOE: PENTOXIFILINA
CAS Nº: 6493-05-6	EC Nº: 229-374-5	AEMPS CODE: 1088A
MOL. WEIGHT: 278,15	MOL. FORMULA: C ₁₃ H ₁₈ N ₄ O ₃	ARTICLE CODE: 1397

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Melting point	103 - 107 °C
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Acidity	=< 0.2 mL of 0.01M NaOH
Related substances	
Impurity A	=< 0.1 %
Impurity C	=< 0.1 %
Impurity F	=< 0.1 %
Impurity J	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 0.5 %
Chlorides	=< 100 ppm
Sulfates	=< 200 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Pentoxifylline 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,

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which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.