



TECHNICAL DATA SHEET

1397-TDS-ENG-2024

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 11.0

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