



TECHNICAL DATA SHEET

521-TDS-ENG-2024

DISULFIRAM (EUR. PH.)		
DESCRIPTION DCI: disulfiram		DESCRIPTION DOE: DISULFIRAM
CAS Nº: 97-77-8	EC Nº: 202-607-8	AEMPS CODE: 1381A
MOL. WEIGHT: 296,55	MOL. FORMULA: C10H20N2S4	ARTICLE CODE: 521

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Melting point	70 - 73 °C
Related substances	
Any other impurity	=< 0.5 %
Diethyldithiocarbamate	=< 150 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Dilsufiram 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.