



## DISULFIRAM (EUR. PH.)

PRODUCT CODE: 521	CAS Nº: 97-77-8	ANALYSIS Nº: 343/25
MANUFACTURER BATCH: MBCQ25008A	CERTIFICATE ID: 48.993	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/10/2025	
METAPH BATCH: 0331025	RETEST DATE: 30/03/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	Almost white crystalline powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Melting point	70 - 73 °C	70.3 °C
Related substances		
Any other impurity	=< 0.5 %	< 0.5 %
Diethyldithiocarbamate	=< 150 ppm	< 150 ppm
Loss on drying	=< 0.5 %	0.01 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	98.5 - 101.0 %	99.0 %

### 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.

Dilsufiram is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(\*) 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. Store the container tightly closed in a dry, well-ventilated place.

Analysis date: 11/11/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001069

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