

## NIAPRAZINA

PRODUCT CODE: 010	CAS N°: 27367-90-4	ANALYSIS N°: 292/24
MANUFACTURER BATCH: NPZ20241001	CERTIFICATE ID: 44.191	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/10/2024	
METAPH BATCH: 0171124	EXPIRY DATE: 30/10/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Solubility	Soluble in ethanol and insoluble in water	Complies (*)
Identification	Complies	Complies
Melting point	130 - 132 °C	131.7 °C
Residue on ignition	= < 0.2 %	0.1 %
Loss on drying	= < 1.0 %	0.2 %
Related substances		
Individual impurities	= < 0.5 %	< 0.5 %
Total impurities	= < 2.0 %	< 2.0 %
Assay	98.0 - 102.0 %	101.1 %
Residual solvents [In-house]		
Acetone	= < 5000 ppm	< 50 ppm
Ethanol	= < 5000 ppm	< 50 ppm
Ethyl acetate	= < 5000 ppm	< 50 ppm
Microbiological control		
TAMC	= < 1000 CFU/g	< 10 CFU/g
TYMC	= < 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Candida Albicans	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

### COMPLIES WITH

Manufacturer Specifications

### REMARKS

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

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

(\*) 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

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

Analysis date: 21/11/2024  
 Signature: Albert Sanchez Lopez (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000349

