METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

010-TDS-ENG-2023

NIAPRAZINE		
DESCRIPTION DCI: NIAPRAZINE	DESCRIPTION DOE: NIAPRAZINA	
CAS Nº: 27367-90-4	EC Nº: 248-431-5	AEMPS CODE: 30922A
MOL. WEIGHT: 356.44	MOL. FORMULA: C20H25FN4O	ARTICLE CODE: 010

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Identification	Complies
Melting point	130 - 132 ºC
Sulfated ash	=< 0.2 %
Loss on drying	=< 1.0 %
Related substances	
Individual impurities	=< 0.5 %
Total impurities	=< 2.0 %
Assay	98.0 - 102.0 %
Residual solvents [In-house]	
Acetone	=< 5000 ppm
Ethanol	=< 5000 ppm
Ethyl acetate	=< 5000 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
Candida Albicans	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

Niaprazine 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.