



TECHNICAL DATA SHEET

151361-TDS-ENG-2023

PENFLURIDOL (In house)		
DESCRIPTION DCI: PENFLURIDOL		DESCRIPTION DOE: PENFLURIDOL
CAS N°: 26864-56-2	EC N°: 248-074-5	AEMPS CODE: 1120A
MOL. WEIGHT: 523.97	MOL. FORMULA: C ₂₈ H ₂₇ ClF ₅ NO	ARTICLE CODE: 151361

ATTRIBUTES	SHOULD BE
Description	White or almost white crystalline powder. Odorless
Identification A	Complies
Identification B	Complies
Melting point	105 - 108 °C
Fluorides	= < 0.02 %
Loss on drying	= < 0.5 %
Related substances	
Total impurities	= < 0.5 %
Residue on ignition	= < 0.1 %
Assay	= > 99.0 %
Residual solvents	
Ethanol	= < 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 container tightly closed in a dry and well-ventilated place.

REMARKS

Penfluridol 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.