



TECHNICAL DATA SHEET

002954-TDS-ENG-2021

PIPAMPERONA DIHIDROCLORURO		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: 2448-68-2	EC N°: 219-507-5	AEMPS CODE: ---
MOL. WEIGHT: 448.46	MOL. FORMULA: C ₂₁ H ₃₀ FN ₃ O ₂ · 2HCl	ARTICLE CODE: 002954

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Identification IR	Complies
Identification UV	Complies
Identification chlorides	Complies
Appearance of solution	Clear
Related substances	
4-chloro-4'-fluoro-butyrophenone	=< 2.5 ppm
4-chloro-butyrophenone	=< 2.5 ppm
4-chloro-2'-fluoro-butyrophenone	=< 2.5 ppm
Impurity 1	=< 0.15 %
Impurity 2	=< 0.15 %
Impurity 3	=< 0.15 %
Any other impurity	=< 0.10 %
Total impurities	=< 0.50 %
Palladium	=< 5 ppm
Water	=< 2.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %
Residual solvents	
Acetone	=< 1000 ppm
Methyl isobutyl ketone	=< 1000 ppm

COMPLIES WITH

Manufacturer Specifications

STORAGE

Preserve in the original packaging tightly closed.

REMARKS

Pipamperone Dihydrochloride 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.