



TECHNICAL DATA SHEET

96-TDS-ENG-2023

ERGOTAMINA TARTRATO (EP)		
DESCRIPTION DCI: ERGOTAMINE TARTRATE		DESCRIPTION DOE: ERGOTAMINA TARTRATO
CAS N°: 379-79-3	EC N°: 206-835-9	AEMPS CODE: 16TB
MOL. WEIGHT: 1313.43	MOL. FORMULA: C70H76N10O16	ARTICLE CODE: 96

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals, slightly hygroscopic
Solubility	Slightly soluble in ethanol 96 %. Aqueous solutions slowly become cloudy owing to hydrolysis; this may be prevented by the addition of tartaric acid
Identification B	Complies
pH	4.0 - 5.5
Related substances	
Impurity C	=< 0.4 %
Impurity A	=< 0.2 %
Impurity B	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.6 %
Loss on drying	=< 6.0 %
Assay	98.0 - 101.0 %
Residual solvents	
Acetone	=< 5000 ppm
Toluene	=< 890 ppm
Methanol	=< 3000 ppm
Particle size	
D10	=< 5 µm
D50	=< 15 µm
D90	=< 40 µm

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

In an airtight container, protected from the light, at a temperature of 2 to 8 °C.

REMARKS

Ergotamine Tartrate 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.