



TECHNICAL DATA SHEET

0271-TDS-ENG-2024

CAFEINA ANHIDRA (EUR. PH.)		
DESCRIPTION DCI: ANHYDROUS CAFFEINE		DESCRIPTION DOE: CAFEINA ANHIDRA
CAS Nº: 58-08-2	EC Nº: 200-362-1	AEMPS CODE: 14ZU
MOL. WEIGHT: 194,19	MOL. FORMULA: C ₈ H ₁₀ N ₄ O ₂	ARTICLE CODE: 0271

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or silky crystals
Solubility	Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol (96 %). It dissolves in concentrated solutions of alkali benzoates or salicylates
Identification A	Complies
Identification B	Complies
Identification E	Complies
Melting point	234 - 239 °C
Appearance of solution	Clear and colourless
Acidity	=< 0.2 mL of 0.01 M NaOH
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.10 %
Sulfates	=< 500 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a well-ventilated, cool and dry place

REMARKS

Caffeine 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.