

CAFEINA ANHIDRA (EUR. PH.)			
PRODUCT CODE: 0271		CAS Nº: 58-08-2	ANALYSIS Nº: 114/22
MANUFACTURER BATCH:	1032112051	CERTIFICATE ID:	34.779
SUPPLIER BATCH:	U0035104	MANUFACTURING DATE:	01/12/2021
METAPH BATCH:	0190422	RETEST DATE:	30/11/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or silky crystals	White crystalline powder (*)
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	Complies
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Identification E	Complies	Complies (*)
Melting point	234 - 239 °C	237 °C (*)
Appearance of solution	Clear and colourless	Complies
Acidity	=< 0.2 mL of 0.01 M NaOH	< 0.20 mL of 0.01 M NaOH
Related substances		
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurities	=< 0.10 %	< 0.10 %
Sulfates	=< 500 ppm	< 500 ppm
Loss on drying	=< 0.5 %	0.05 % (*)
Sulfated ash	=< 0.1 %	0.03 %
Assay	98.5 - 101.5 %	101.1 % (*)

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Anhydrous 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.

(*) Data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 31/05/2022
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000509
 CSPC INNOVATION PHARM. CO. LTD.
 Fuqiang West Road, Luancheng,, 36
 051430 Shijiazhuang
 Hebei(Xina)

