



TECHNICAL DATA SHEET

010709-TDS-ENG-2020

CHLOROQUINE PHOSPHATE (EP)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 50-63-5	EC Nº: 200-055-2	AEMPS CODE: ---
MOL. WEIGHT: 515.90	MOL. FORMULA: C ₁₈ H ₂₆ CIN ₃ ·2H ₃ PO ₄	ARTICLE CODE: 010709

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder, hygroscopic
Solubility	Freely soluble in water, very slightly soluble in alcohol and in methanol
Melting point	about 195 °C
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY5 o GY5
pH	3.8 - 4.3
Related substances	
Single impurities	=< 1.0 %
Any other impurity	=< 0.5 %
Loss on drying	=< 2.0 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep the container tightly closed in a fresh, dry and well-ventilated place.

REMARKS

Chloroquine Phosphate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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.