



TECHNICAL DATA SHEET

110170-TDS-ENG-2020

HYDROXYCHLOROQUINE SULFATE (EP)		
DESCRIPTION DCI: HYDROXYCHLOROQUINE SULFATE		DESCRIPTION DOE: HIDROXICLOROQUINA SULFATO
CAS Nº: 747-36-4	EC Nº: 212-019-3	AEMPS CODE: ---
MOL. WEIGHT: 433.96	MOL. FORMULA: C ₁₈ H ₂₈ ClN ₃ O ₅ S	ARTICLE CODE: 110170

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, crystalline powder
Solubility	Freely soluble in water, practically insoluble in ethanol (96 per cent) and in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Related substances	
Impurity C	=< 0.4 %
Impurity B	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.6 %
Loss on drying	=< 2.0 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %
Residual solvents	
Ethanol	=< 0.5 %
Methanol	=< 0.2 %
Acetone	=< 0.2 %
Ethyl acetate	=< 0.2 %
1,4-Dioxane	=< 0.038 %
Particle size	
> 150 µm	=< 20 %

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

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

REMARKS

Hydroxychloroquine Sulfate 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.