METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1082-TDS-ENG-2024

HIDROCLOROTIAZIDA (EUR. PH.)		
DESCRIPTION DCI: HYDROCHLOROTHIAZIDE	DESCRIPTION DOE: HIDROCLOROTIAZIDA	
CAS Nº: 58-93-5	EC Nº: 200-403-3	AEMPS CODE: 1343A
MOL. WEIGHT: 297.7	MOL. FORMULA: C7H8ClN3O4S2	ARTICLE CODE: 1082

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides.
Identification B	Complies
Acidity or alcalinity	=< 0.4 mL of HCl 0.01M
Related substances	
Impurities A, B, and C	=< 0.5 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.0 %
Chlorides	=< 100 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

REMARKS

Hydrochlorothiazide 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.