METAPHARMACEUTICAL IND SL
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HIDROCLOROTIAZIDA (EUR. PH.)

PRODUCT CODE: 1082	CAS Nº: 58-93-5	ANALYSIS Nº: 206/24	
MANUFACTURER BATCH:	24020HC10RII	CERTIFICATE ID:	43.174
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/03/2024
METAPH BATCH:	0010824	EXPIRY DATE:	28/02/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	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.	Complies (*)
Identification B	Complies	Complies
Acidity or alcalinity	=< 0.4 mL of HCl 0.01M	0.38 mL of 0.01M HCl
Related substances		
Impurity A	=< 0.5 %	< 0.05 %
Impurity B	=< 0.5 %	0.05 %
Impurity C	=< 0.5 %	0.06 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.1 %
Chlorides	=< 100 ppm	< 100 ppm
Loss on drying	=< 0.5 %	0.3 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	97.5 - 102.0 %	98.3 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

It shows polymorphism.

Hydrochlorothiazide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 07/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000356