METAPHARMACEUTICAL IND SL
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CETIRIZINA DIHIDROCLORURO (EUR. PH.)

PRODUCT CODE: 010294	CAS Nº: 83881-52-1	ANALYSIS Nº: 005/25	
MANUFACTURER BATCH:	24046CZ6RII	CERTIFICATE ID:	44.649
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/09/2024
METAPH BATCH:	0050125	EXPIRY DATE:	30/08/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Freely soluble in water, practically insoluble in acetone and in methylene chloride	Complies (*)
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
pH	1.2 - 1.8	1.5
Related substances		
Impurity A	=< 0.15 %	Not Detected
Impurity B	=< 0.15 %	< 0.05 %
Impurity C	=< 0.15 %	< 0.05 %
Impurity D	=< 0.15 %	Not Detected
Impurity E	=< 0.15 %	< 0.05 %
Impurity F	=< 0.15 %	0.11 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	0.11 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.2 %	0.1 %
Assay	99.0 - 101.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Cetirizine Dihydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) 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

Keep in a tightly closed container, in a cool and a dry place protected from light.

Analysis date: 19/02/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000356
IPCA LABORATORIES LIMITED
A-1/7 & A-1/8 Phase a, GIDC
396195 Vapi
(Índia)