

PROMETAZINA HCL (EUR. PH.)

PRODUCT CODE: 1499	CAS Nº: 58-33-3	ANALYSIS Nº: 121/25
MANUFACTURER BATCH: HPHCPS105	CERTIFICATE ID: 46.386	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/03/2025	
METAPH BATCH: 0070525	EXPIRY DATE: 28/02/2030	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or faintly yellowish, crystalline powder	White crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %) and in methylene chloride	Complies (*)
Melting point	About 222 °C, with decomposition	222.4 °C (*)
Identification A	Complies	Complies
Identification D	Complies	Complies
pH	4.0 - 5.0	4.5
Related substances		
Impurity B	=< 0.8 %	0.3 %
Impurity C	=< 0.2 %	0.1 %
Impurity A	=< 0.1 %	Not Detected
Impurity D	=< 0.1 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.06 % (RT = 10.38 min)
Total impurities	=< 1.2 %	0.5 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	99.0 - 101.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

All data controlled by Metapharmaceutical Industrial SL.

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

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

Analysis date: 27/05/2025
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000345
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