



PROMETAZINA HCL (EUR. PH.)

PRODUCT CODE: 1499	CAS Nº: 58-33-3	ANALYSIS Nº: 108/24
MANUFACTURER BATCH: HPHCPR104	CERTIFICATE ID: 41.907	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/03/2024	
METAPH BATCH: 0200424	RETEST DATE: 28/02/2029	

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	221 °C
Identification A	Complies	Complies
Identification D	Complies	Complies
pH	4.0 - 5.0	4.2
Related substances		
Impurity B	=< 0.8 %	0.4 %
Impurity C	=< 0.2 %	0.1 %
Impurity A	=< 0.1 %	Not Detected
Impurity D	=< 0.1 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.2 %	0.5 %
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

Analysis date: 14/05/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000345
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