



PROCARBAZINA HCL (USP)

PRODUCT CODE: 46433075	CAS Nº: 366-70-1	ANALYSIS Nº: 309/25
MANUFACTURER BATCH: PRH20250701	CERTIFICATE ID: 48.526	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 11/07/2025	
METAPH BATCH: 0011025	EXPIRY DATE: 10/07/2028	

ATTRIBUTES	SHOULD BE	IS
Identification A	Complies	Complies
Identification B	Complies	Complies
Residue on ignition	=< 0.1 %	0.06 %
Assay	98.5 - 100.5 %	99.0 %

COMPLIES WITH

USP 2025

REMARKS

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

Procabazine Hydrochloride 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".

All data controlled by Metapharmaceutical Industrial SL.

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: 20/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
H. G. (WAICOME PHARMA)
No. 138 YuWu Road
XinMin Town
408302 Chongqing