



TECHNICAL DATA SHEET

46433075-TDS-ENG-2025

PROCARBAZINA HCL (USP)		
DESCRIPTION DCI: PROCARBAZINE HYDROCHLORIDE		DESCRIPTION DOE: PROCARBAZINA HIDROCLORURO
CAS Nº: 366-70-1	EC Nº: 206-678-6	AEMPS CODE: 651CH
MOL. WEIGHT: 257,76	MOL. FORMULA: C ₁₂ H ₂₀ ClN ₃ O	ARTICLE CODE: 46433075

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

COMPLIES WITH

USP 2025

STORAGE

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

REMARKS

Procarbazine 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".

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.