

Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-B117956B-5764-49E1-BC95-64630E8CE7E2_1_en-US
DOI: https://doi.org/10.31003/USPNF_M69540_01_01
DOI Ref: ojh98

© 2025 USPC
Do not distribute

Procarbazine Hydrochloride Capsules

» Procarbazine Hydrochloride Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of procarbazine ($C_{12}H_{19}N_3O$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11)—
[USP Procarbazine Hydrochloride RS](#)

Identification—The polarogram of the solution employed for measurement in the Assay exhibits a half-wave potential ($E_{1/2}$) within ± 0.03 volt of that of [USP Procarbazine Hydrochloride RS](#), similarly measured ($E_{1/2}$ is about -0.16 volt against a saturated calomel electrode).

DISSOLUTION (711)—

Medium: water; 900 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.

Procedure—Determine the amount of procarbazine ($C_{12}H_{19}N_3O$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 233 nm of filtered portions of the solution under test, suitably diluted with water, in comparison with a Standard solution having a known concentration of [USP Procarbazine Hydrochloride RS](#) in the same medium.

Tolerances—Not less than 75% (Q) of the labeled amount of $C_{12}H_{19}N_3O$ is dissolved in 45 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay—

pH 12 buffer—Dissolve 5.43 mL of phosphoric acid, 4.60 mL of glacial acetic acid, and 4.95 g of boric acid in water to make 2000 mL. To 100 mL of this solution add 100 mL of 0.2 N sodium hydroxide. Prior to use, deaerate this solution by bubbling with scrubbed nitrogen.

Procedure—[NOTE—Use low-actinic glassware throughout this procedure.] Weigh the contents of not less than 20 Capsules, and determine the average weight per capsule. Mix the combined contents to obtain a homogeneous sample. Transfer an accurately weighed portion of this powder, equivalent to about 60 mg of procarbazine hydrochloride, to a 100-mL volumetric flask that previously has been flushed with nitrogen. Dissolve in *pH 12 buffer*, dilute with *pH 12 buffer* to volume, and centrifuge a portion of this solution at about 1500 rpm for about 3 minutes. Transfer 10 mL to 15 mL of the solution to a polarographic cell that is regulated at $25 \pm 0.1^\circ$. Deaerate by bubbling scrubbed nitrogen through the solution for 5 minutes. Insert the dropping mercury electrode of a suitable polarograph, which is capable of measuring a current of 10 microamperes, using an average capillary, a mercury column height of 56 cm, and a drop rate of approximately 4 per second. Record the polarogram from -0.75 volt to $+0.25$ volt, using a saturated calomel electrode as the reference electrode. Determine the height of the current at a point 200 mV anodic of the half-wave potential. Calculate the quantity, in mg, of $C_{12}H_{19}N_3O$ in the portion of Capsule contents taken by the formula:

$$100(0.8585C)[i_u/i_s]$$

in which 0.8585 is the ratio of the molecular weight of procarbazine to that of procarbazine hydrochloride, i_u is the observed current of the solution from the Capsule contents and i_s is that determined similarly in a solution of [USP Procarbazine Hydrochloride RS](#), the concentration of which is C mg per mL (about 600 μ g per mL).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PROCARBAZINE HYDROCHLORIDE CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-B117956B-5764-49E1-BC95-64630E8CE7E2_1_en-US

DOI: https://doi.org/10.31003/USPNF_M69540_01_01

DOI ref: [ojh98](#)

OFFICIAL