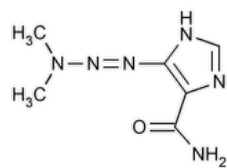


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Dacarbazine



$C_6H_{10}N_6O$ 182.18
1*H*-Imidazole-4-carboxamide, 5-(3,3-dimethyltriaz-1-enyl)-;
5-(3,3-Dimethyltriaz-1-enyl)-1*H*-imidazole-4-carboxamide CAS RN®: 4342-03-04.

DEFINITION

Dacarbazine contains NLT 97.0% and NMT 102.0% of dacarbazine ($C_6H_{10}N_6O$).

[**CAUTION**—Great care should be taken in handling Dacarbazine, as it is a potent cytotoxic agent.]

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Protect solutions containing dacarbazine from light and store at 2°–8°.

Solution A: 4.1 g/L of [sodium acetate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 7.0.

Solution B: 4.1 g/L of [sodium acetate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 5.5. Mix [acetonitrile](#) and this solution (25:75).

Mobile phase: See [Table 1](#). Return to original conditions, and equilibrate the system for 10 min.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
10	100	0
20	5	95
23	5	95
25	100	0
35	100	0

Diluent: 0.1 mg/mL of [citric acid](#) in [water](#)
Standard solution: 0.1 mg/mL of [USP Dacarbazine RS](#) in *Diluent*
Sample solution: 0.1 mg/mL of Dacarbazine in *Diluent*
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC**Detector:** UV 250 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)**Autosampler temperature:** 2°–8°**Flow rate:** 1.0 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of dacarbazine ($C_6H_{10}N_6O$) in the portion of Dacarbazine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Dacarbazine RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Dacarbazine in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0%**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- **ORGANIC IMPURITIES**

Protect solutions containing dacarbazine and its related compounds from light and store at 2°–8°.

Solution A, Solution B, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.**Diluent:** 4.0 mg/mL of [citric acid](#) in [water](#)**Standard stock solution:** Use the *Standard solution*, prepared as directed in the Assay.**Standard solution:** 4.0 μg/mL of [USP Dacarbazine RS](#) prepared as follows. Transfer a suitable amount of *Standard stock solution* into a volumetric flask and dilute with [water](#).**Dacarbazine related compound A standard solution:** 0.04 mg/mL of [USP Dacarbazine Related Compound A RS](#) in [water](#). Sonicate to ensure complete dissolution.**Dacarbazine related compound B standard solution:** 0.04 mg/mL of [USP Dacarbazine Related Compound B RS](#) in [water](#). Sonicate to ensure complete dissolution.**Sensitivity solution:** 2.0 μg/mL of [USP Dacarbazine RS](#) in [water](#) from *Standard solution***Sample solution:** 4.0 mg/mL of Dacarbazine in *Diluent*. Sonicate to ensure complete dissolution.**System suitability****Samples:** *Dacarbazine related compound A standard solution*, *Dacarbazine related compound B standard solution*, and *Sensitivity solution***Suitability requirements****Relative standard deviation 1:** NMT 5.0%, *Dacarbazine related compound A standard solution***Relative standard deviation 2:** NMT 5.0%, *Dacarbazine related compound B standard solution***Signal-to-noise ratio:** ▲NLT ▲ (ERR 1-Dec-2021) 10, *Sensitivity solution***Analysis****Samples:** *Standard solution*, *Dacarbazine related compound A standard solution*, *Dacarbazine related compound B standard solution*, and *Sample solution*Calculate the percentage of 5-aminoimidazole-4-carboxamide (free base of [USP Dacarbazine Related Compound A RS](#)) in the portion of Dacarbazine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$