

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-849C368B-DB82-4ED6-BCA6-4C4C943599A0_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M60195_05_01
 DOI Ref: og69q

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Change to read:

▲ Paclitaxel ▲ (ERR 1-May-2021) Injection

DEFINITION

Paclitaxel Injection is a sterile, stabilized solution of Paclitaxel, suitable for dilution for intravenous administration. It contains NLT 90.0% and NMT 110.0% of the labeled amount of paclitaxel ($C_{47}H_{51}NO_{14}$).

IDENTIFICATION

Change to read:

- **A.**▲ The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2021)
- **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

Change to read:

• PROCEDURE

Diluent: To a volumetric flask, add 50% of the flask volume of [methanol](#) and then add 0.02% of the flask volume of [acetic acid, glacial](#). Dilute with [methanol](#) to volume.

Mobile phase: [Acetonitrile](#) and [water](#) (45:55)

Standard solution: 0.6 mg/mL of [USP Paclitaxel RS](#) in *Diluent*

Sample solution: Nominally 0.6 mg/mL of paclitaxel from Injection in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 227 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2021)

Column: 4.0-mm × 25-cm; 5-μm packing [L43](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Retention time: 6.0–10.0 min

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of paclitaxel ($C_{47}H_{51}NO_{14}$) in the portion of Injection taken:▲ (USP 1-May-2021)

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

r_U = peak response of paclitaxel from the *Sample solution*

r_S = peak response of paclitaxel from the *Standard solution*

C_S = concentration of [USP Paclitaxel RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of paclitaxel in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES**Change to read:**

- ▲ **ORGANIC IMPURITIES** ▲ (USP 1-MAY-2021)

Solution A: [Acetonitrile](#) and [water](#) (40:60)**Solution B:** [Acetonitrile](#)**Mobile phase:** See [Table 1](#).**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	100	0
26	100	0
66	17	83
67	100	0
75	100	0

Standard solution: 1.2 mg/mL of [USP Paclitaxel RS](#) and 0.006 mg/mL of [USP Paclitaxel Related Compound B RS](#) in [acetonitrile](#)**Sample solution:** Nominally 1.2 mg/mL of paclitaxel from Injection in [acetonitrile](#)**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 227 nm**Column:** 4.6-mm × 15-cm; 3-µm packing [L1](#)**Column temperature:** 35°**Flow rate:** 1.2 mL/min**Injection volume:** 10 µL**System suitability****Sample:** *Standard solution*[NOTE—See [Table 2](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 1.2 between the paclitaxel related compound B and paclitaxel peaks**Relative standard deviation:** NMT 2.0% ▲ for paclitaxel ▲ (USP 1-May-2021)**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Injection taken:

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

 r_U = peak response of each degradation product from the *Sample solution* r_S = peak response of paclitaxel related compound B from the *Standard solution* C_S = concentration of [USP Paclitaxel Related Compound B RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of paclitaxel in the *Sample solution* (mg/mL)**Acceptance criteria:** See [Table 2](#).**Table 2**