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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

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Baccatin III▲[a]▲ (USP 1-May-2021)	0.19	0.8
Ethyl ester side chain▲[b]▲ (USP 1-May-2021)	0.21	0.4
10-Deacetylpaclitaxel▲[c]▲ (USP 1-May-2021)	0.50	0.8
▲▲ (USP 1-May-2021) Paclitaxel related compound B	0.95	0.5
▲Paclitaxel	1.0	—▲ (USP 1-May-2021)
7-Epipaclitaxel▲[d]▲ (USP 1-May-2021)	1.4▲▲ (USP 1-May-2021)	0.6
Any other degradation product	—	0.1
Total degradation products	—	2.0

[a] (2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-12-(Benzoyloxy)-4,9,11-trihydroxy-4a,8,13,13-tetramethyl-5-oxo-3,4,4a,5,6,9,10,11,12,12a-decahydro-1*H*-7,11-methanocyclodeca[3,4]benzo[1,2-*b*]oxete-6,12b(2a*H*)-diyl diacetate.

[b] Ethyl (2*R*,3*S*)-3-benzamido-2-hydroxy-3-phenylpropanoate.

[c] (2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12b*S*)-12b-Acetoxy-9-(((2*R*,3*S*)-3-benzamido-2-hydroxy-3-phenylpropanoyl)oxy)-4,6,11-trihydroxy-4a,8,13,13-tetramethyl-5-oxo-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-1*H*-7,11-methanocyclodeca[3,4]benzo[1,2-*b*]oxet-12-yl benzoate.

[d] (2a*R*,4*R*,4a*S*,6*R*,9*S*,11*S*,12*S*,12b*S*)-9-(((2*R*,3*S*)-3-Benzamido-2-hydroxy-3-phenylpropanoyl)oxy)-12-(benzoyloxy)-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-3,4,4a,5,6,9,10,11,12,12a-decahydro-1*H*-7,11-methanocyclodeca[3,4]benzo[1,2-*b*]oxete-6,12b(2a*H*)-diyl diacetate.

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test ⟨85⟩:** ▲Meets the requirements▲ (USP 1-May-2021)

• **pH ⟨791⟩**

Sample: 1 in 10

Acceptance criteria: 3.0–7.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, at controlled room temperature.

▲Protect from light.▲ (USP 1-May-2021)

• **Labeling:** Label it to indicate that it is to be diluted with a suitable parenteral vehicle before intravenous infusion.

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Paclitaxel RS

USP Paclitaxel Related Compound B RS

10-Deacetyl-7-epipaclitaxel.

▲$C_{45}H_{49}O_{13}N$ 811.87▲ (USP 1-May-2021)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PACLITAXEL INJECTION	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

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