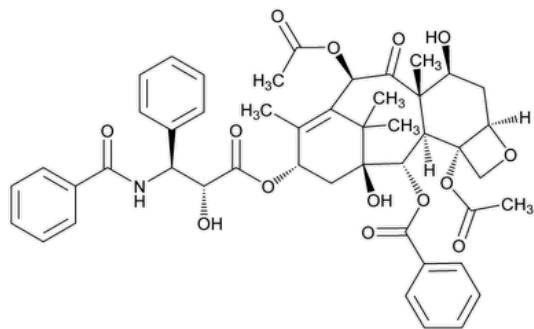


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Paclitaxel



$C_{47}H_{51}NO_{14}$ 853.92

Benzenepropanoic acid, β -(benzoylamino)- α -hydroxy-, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1*H*-cyclodeca[3,4]benz[1,2-*b*]oxet-9-yl ester, [2a*R*-[2a α ,4 β ,4a β ,6 β ,9 α (α *R*^{*}, β *S*^{*}),11 α ,12 α ,12a α ,12b α]];

(2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4,6,9,11,12,12b-hexahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5*H*-cyclodeca[3,4]-benz[1,2-*b*]oxet-5-one 6,12b-diacetate, 12-benzoate, 9-ester with (2*R*,3*S*)-*N*-benzoyl-3-phenylisoserine;

(2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12a*R*,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 CAS RN[®]: 33069-62-4; UNII: P88XT4IS4D.

DEFINITION

Paclitaxel contains NLT 97.0% and NMT 102.0% of paclitaxel ($C_{47}H_{51}NO_{14}$), calculated on the anhydrous and solvent-free basis.

[CAUTION—Paclitaxel is cytotoxic. Great care should be taken to prevent inhaling particles of Paclitaxel and exposing the skin to it.]

IDENTIFICATION

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 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

Diluent: [Methanol](#) and [acetic acid](#) (200:1)

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

Standard solution: 1 mg/mL of [USP Paclitaxel RS](#) in *Diluent*. Sonicate to dissolve if necessary.

Sample solution: 1 mg/mL of Paclitaxel in *Diluent*. Sonicate to dissolve if necessary.

Chromatographic system

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

Mode: LC

Detector: UV 227 nm

Column: 4.6-mm × 25-cm; 5- μ m packing [L43](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.7–1.3

Relative standard deviation: NMT 1.5%

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of paclitaxel ($C_{47}H_{51}NO_{14}$) in the portion of Paclitaxel taken:

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

 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 = concentration of Paclitaxel in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0%, on the anhydrous and solvent-free basis**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Change to read:

- **ORGANIC IMPURITIES**

Test 1 (for material labeled as isolated from natural sources): If the material complies with this test, the labeling indicates that it meets the requirements of USP *Organic Impurities Test 1*.

Solution A: [Acetonitrile](#)**Solution B:** [Water](#)**Mobile phase:** See [Table 1](#).**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	35	65
35	35	65
60	80	20
70	35	65
80	35	65

Diluent: [Methanol](#) and [acetic acid](#) (200:1)**System suitability stock solution:** 10 µg/mL each of [USP Paclitaxel Related Compound A RS](#) and [USP Paclitaxel Related Compound B RS](#) in [methanol](#)**System suitability solution:** 1 µg/mL each of [USP Paclitaxel Related Compound A RS](#) and [USP Paclitaxel Related Compound B RS](#) from *System suitability stock solution* in *Diluent***Standard solution:** 5 µg/mL of [USP Paclitaxel RS](#) in *Diluent*. Sonicate to dissolve if necessary.**Sample solution:** 1 mg/mL of Paclitaxel in *Diluent*. Sonicate to dissolve if necessary.**Chromatographic system**(See [Chromatography \(621\)](#), *System Suitability*.)**Mode:** LC**Detector:** UV 227 nm**Column:** 4.6-mm × 25-cm; 5-µm packing [L43](#)**Column temperature:** 30°**Flow rate:** 2.6 mL/min**Injection volume:** 15 µL**System suitability****Samples:** *System suitability solution* and *Standard solution*[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements**Resolution:** NLT 1.0 between paclitaxel related compound A and paclitaxel related compound B, *System suitability solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Analysis****Sample:** *Sample solution*

Calculate the percentage of each specified and unspecified impurity in the portion of Paclitaxel taken:

$$\text{Result} = (r_U/r_S) \times 1/F \times 100$$

 r_U = peak response of each individual impurity r_S = peak response of paclitaxel F = relative response factor for each individual impurity (see [Table 2](#))**Acceptance criteria:** See [Table 2](#).**Table 2**

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Baccatin III ^a	0.24	0.78	0.2
10-Deacetylpaclitaxel ^b	0.53	1.00	0.5
7-Xylosylpaclitaxel ^c	0.57	1.00	0.2
Paclitaxel related compound A	0.78	0.79	a_1 ^d
Paclitaxel sec-Butyl analog ^e	0.78	0.79	a_2 ^d
Paclitaxel related compound B	0.86	1.00	0.5
Paclitaxel	1.00	—	—
Paclitaxel benzyl analog ^f	1.10	1.00	b_1 ^g
3",4"-Dehydro paclitaxel C ^h	1.10	1.00	b_2 ^g
7-Epicephalomannine ⁱ	1.40	1.00	0.3
7-Epipaclitaxel ^j	1.85	1.00	0.5
Any unspecified impurity	—	1.00	0.1
Total impurities	—	—	2.0

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

^b (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-Acetoxy-9-(((2R,3S)-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-1H-7,11-methanocyclodeca[3,4]benzo[1,2-b]oxet-12-yl benzoate.

^c (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-9-(((2R,3S)-3-Benzamido-2-hydroxy-3-phenylpropanoyl)oxy)-12-(benzoyloxy)-11,12-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-4-(D-xylopyranosyloxy)-3,4,4a,5,6,9,10,11,12,12a-decahydro-1H-7,11-methanocyclodeca[3,4]benzo[1,2-b]oxet-12-yl diacetate.