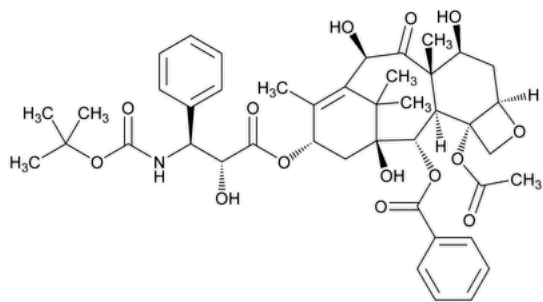


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Docetaxel



$C_{43}H_{53}NO_{14} \cdot 3H_2O$ 861.93
Anhydrous 807.88
Benzenepropanoic acid, β-[[[(1,1-dimethylethoxy) carbonyl]amino]-α-hydroxy-, 12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,6,11-trihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2α,4β,4aβ,6β,9α(αR*,βS*),11α,12α,12aα,12bα]]-;(2R,3S)-N-Carboxy-3-phenylisoserine, N-tert-butyl ester, 13-ester with 5β,20-epoxy-1,2α,4,7β,10β,13α-hexahydroxytax-11-en-9-one 4-acetate 2-benzoate;
Trihydrate CAS RN®: 148408-66-6; UNII: 15H5577CQD.
Anhydrous CAS RN®: 114977-28-5; UNII: 699121PHCA.

DEFINITION
Docetaxel contains NLT 97.5% and NMT 102.0% of docetaxel ($C_{43}H_{53}NO_{14}$), calculated on the anhydrous and solvent-free basis. [CAUTION—
Docetaxel is cytotoxic. Great care should be taken to prevent inhaling particles of Docetaxel and exposing the skin to it.]

IDENTIFICATION
• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A, 197K, 197M, or 197S
[NOTE—Use a solution containing 60 mg/mL of Docetaxel in [methylene chloride](#) for (197S).]
• **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**
Solution A: [Water](#)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	72	28
9.0	72	28
39.0	28	72
39.1	72	28
50	72	28

Diluent: [Acetonitrile](#), [water](#), and glacial acetic acid (100:100:0.1)
System suitability solution: 1 mg/mL of [USP Docetaxel Identification RS](#) in *Diluent*. [NOTE—[USP Docetaxel Identification RS](#) contains docetaxel and small amounts of 2-debenzoyl 2-pentenoyl docetaxel, 6-oxodocetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel. See [Table 2](#).]

Standard solution: 1.0 mg/mL of [USP Docetaxel RS](#) prepared as follows. Transfer a quantity of [USP Docetaxel RS](#) to a suitable volumetric flask, dissolve in [alcohol](#) equivalent to about 5% of the final volume, and dilute with *Diluent* to volume.

Sample solution: 1.0 mg/mL of Docetaxel prepared as follows. Transfer a quantity of Docetaxel to a suitable volumetric flask, dissolve in [alcohol](#) equivalent to about 5% of the final volume, and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 232 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Temperatures

Autosampler: 10°

Column: 45°

Flow rate: 1.2 mL/min

Injection volume: 10 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3.5 between 2-debenzoxyl 2-pentenoyl docetaxel and docetaxel, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of docetaxel ($C_{43}H_{53}NO_{14}$) in the portion of Docetaxel 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 Docetaxel RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.5%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

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

Change to read:

• **ORGANIC IMPURITIES, PROCEDURE 1**

[NOTE—On the basis of the synthetic route, perform either *Procedure 1* or *Procedure 2*. *Procedure 1* is recommended if 10-deacetyl baccatin and 2-debenzoxyl 2-pentenoyl docetaxel are specified impurities. *Procedure 2* is recommended if O-BOC *N*-pyruvyl docetaxel is a specified impurity.]

▲ **Mobile phase, Diluent,** ▲ (ERR 1-Jun-2024) **System suitability solution, Standard solution, Sample solution, and Chromatographic system:** Proceed as directed in the Assay.

Sensitivity solution: 0.5 μg/mL of [USP Docetaxel RS](#) in *Diluent* from the *Standard solution*

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 3.5 between 2-debenzoxyl 2-pentenoyl docetaxel and docetaxel, *System suitability solution*

Signal-to-noise ratio: NLT 10 for the docetaxel peak, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Docetaxel taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

r_T = sum of all peak responses from the *Sample solution*

F = relative response factor for each individual impurity (see [Table 2](#))