exchange column, and collecting the eluate in a 50-mL volumetric flask. Dilute with water to volume, and mix.

Procedure—Determine the absorbance of the *Test solution* in a 1-cm cell at 284 nm, with a suitable spectrophotometer, after correcting for the *Blank solution:* the absorbance is not more than 0.25.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay for dextrose—Determine the angular rotation of Injection (see *Optical Rotation* ⟨781⟩). Calculate the per centage (g per 100 mL) of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken by the formula:

$$(100/52.9)(198.17/180.16)AR$$

in which 100 is the per centage; 52.9 is the midpoint of the specific rotation range for anhydrous dextrose, in degrees; 198.17 and 180.16 are the molecular weights for dextrose monohydrate and anhydrous dextrose, respectively; *A* is 100 mm divided by the length of the polarimeter tube, in mm; and *R* is the obser ved rotation, in degrees.

Assay for dobutamine—

Phosphate buffer, Mobile phase, Standard preparation, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Dobutamine Hydrochloride*.

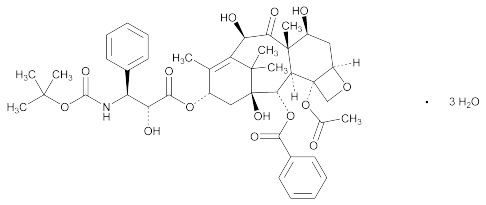
Assay preparation—Transfer an amount of Dobutamine in Dextrose Injection, equivalent to about 44.6 mg of dobutamine, accurately weighed, to a 100-mL volumetric flask, dilute with water to volume, and mix. [NOTE—Refrigerate until injected, and use within 8 hours.]

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of dobutamine ($C_{18}H_{23}NO_3$) in the portion of Dobutamine in Dextrose Injection taken by the formula:

$$(301.39/337.84)100C(r_U / r_S)$$

in which 301.39 and 337.84 are the molecular weights of dobutamine and dobutamine hydrochloride, respectively; *C* is the concentration, in mg per mL, of USP Dobutamine Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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-1*H*-cyclodeca[3,4]benz[1,2-*b*]oxet-9-yl ester trihydrate, [2a*R*-[2aα,4β,4aβ,6β,9α(α*R**,β*S**),11α,12α,12aα,12bα]]-;(2*R*,3*S*)-*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 [148408-66-6].

DEFINITION

Docetaxel contains NLT 97.5% and NMT 102.0% of $C_{43}H_{53}NO_{14}$, 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. INFRARED ABSORPTION ⟨197⟩**
  [NOTE—Methods described under *Infrared Absorption* ⟨197K⟩, ⟨197M⟩, or ⟨197S⟩ may be used. Use 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 the gradient table below.

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 acetic acid (100:100:0.1)
Standard solution: 1.0 mg/mL made by transferring a quantity of USP Docetaxel RS to a suitable volumetric flask, dissolving in alcohol, equivalent to about 5% of the final volume, and diluting with *Diluent* to volume
System suitability solution: 1 mg/mL of USP Docetaxel Identification RS in *Diluent*. [NOTE—USP Docetaxel Identification RS contains docetaxel and a small amount of 2-debenzoxyl 2-pentenoyl docetaxel, 6-oxodocetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel. See *Impurity Table 1*.]
Sample solution: 1.0 mg/mL made by transferring a quantity of Docetaxel to a suitable volumetric flask, dissolving in alcohol, equivalent to about 5% of the final volume, and diluting with *Diluent* to volume
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 232 nm
Refrigerated autosampler temperature: 10°
Column: 4.6-mm × 15-cm; 3.5-µm packing L1
Column temperature: 45°
Flow rate: 1.2 mL/min
Injection size: 10 µL
System suitability
Samples: *Standard solution* and *System suitability solution*
Suitability requirements
Resolution: NLT 4 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 per centage of $C_{43}H_{53}NO_{14}$ 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 docetaxel 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

Inorganic Impurities

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
- **HEAVY METALS,** *Method I* ⟨**231**⟩
  Sample solution: Dissolve 1 g in 20 mL of a mixture of dimethylformamide and water (17:3). To 12 mL of this solution, add 2 mL of *pH 3.5 Acetate Buffer* and mix. Add 1.2 mL of thioacetamide–glycerin base TS and mix.
  Acceptance criteria: NMT 20 ppm

Organic Impurities

- **PROCEDURE**
  Standard solution, System suitability 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 4 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 the responses of all peaks from the *Sample solution*
F = relative response factor for each individual impurity (see *Impurity Table 1*)

  Acceptance criteria
  Individual impurities: See *Impurity Table 1*. [NOTE—Disregard any impurity peaks less than 0.05%.]
  Total impurities: NMT 1.0%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
2-Debenzoxyl 2-pentenoyl docetaxel[a]	0.97	0.63	0.5
Docetaxel	1.00	—	—
6-Oxodocetaxel[b]	1.08	1.0	0.3
4-Epidocetaxel[c]	1.13	1.0	0.3
4-Epi-6-oxodocetaxel[d]	1.18	1.0	0.2
Any unspecified impurity	—	1.0	0.10

[a] (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 12b-acetate, 12-[(*E*)-2-methylbut-2-enoate], 9-ester with (2 *R*,3*S*)-*N*-*tert*-butoxycarbonyl-3-phenylisoserine.
[b] (2a*R*,4*S*,4a*S*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4, 9,11,12,12b-pentahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5*H*-cyclodeca[3,4]benz[1,2-*b*]oxet-5,6-dione 12b-acetate, 12-benzoate, 9-ester with (2 *R*,3*S*)-*N*-*tert*-butoxycarbonyl-3-phenylisoserine.
[c] (2a*R*,4*R*,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 12b-acetate, 12-benzoate, 9-ester with (2 *R*,3*S*)-*N*-*tert*-butoxycarbonyl-3-phenylisoserine.
[d] (2a*R*,4*R*,4a*S*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4, 9,11,12,12b-pentahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5*H*-cyclodeca[3,4]benz[1,2-*b*]oxet-5,6-dione 12b-acetate, 12-benzoate, 9-ester with (2 *R*,3*S*)-*N*-*tert*-butoxycarbonyl-3-phenylisoserine.

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS ⟨61⟩** and **TESTS FOR SPECIFIED MICROORGANISMS ⟨62⟩:** The total aerobic microbial limit does not exceed 100 cfu/g. The total yeast and mold count does not exceed 10 cfu/g.
- **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** It contains NMT 0.3 USP Endotoxin Units/mg.
- **WATER DETERMINATION,** *Method Ic* ⟨**921**⟩**:** 5.0%–7.0%
- **OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩**:** −39° to −41° (t=20°), calculated on the anhydrous and solvent-free basis.
  Sample solution: 10 mg/mL in methanol

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well closed, light-resistant containers, and store at room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Docetaxel RS
  USP Docetaxel Identification RS
  Contains docetaxel and small amount of 2-debenzoxyl 2-pentenoyl docetaxel, 6-oxodocetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel.
  USP Endotoxin RS

Add the following:

▲Docetaxel Injection

DEFINITION

Docetaxel Injection is a sterile solution of Docetaxel. It contains NLT 90.0% and NMT 110.0% of the labeled amount of docetaxel (anhydrous) ($C_{43}H_{53}NO_{14}$). It contains polysorbate 80 and/or other suitable solubilizing agents in the infusion vehicle. It may also contain dehydrated alcohol.

IDENTIFICATION

- **A. THIN-LAYER CHROMOTOGRAPHIC IDENTIFICATION TEST ⟨201⟩**
  Standard solution: 0.4 mg/mL of USP Docetaxel RS in methylene chloride containing 1% (v/v) of polysorbate 80
  Sample solution: 0.4 mg/mL of docetaxel (anhydrous) in methylene chloride, from Injection
  Adsorbent: 0.25-mm layer of chromatographic silica gel mixture containing a fluorescent indicator