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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.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- B.** The UV spectrum 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	0	100
49.0	0	100
49.1	72	28
60	72	28

Diluent: Acetonitrile, glacial acetic acid, and [water](#) (100:0.1:100)

System suitability solution: 1 mg/mL of [USP Docetaxel Identification RS](#) in *Diluent*

Standard solution: 0.2 mg/mL of [USP Docetaxel RS](#). Transfer [USP Docetaxel RS](#) into a suitable volumetric flask, and dissolve in [alcohol](#) equivalent to 5% of the final volume. Dilute with *Diluent* to volume.

Sample solution (for Injection labeled as one-vial formulation): Dilute a portion of the Injection with *Diluent* to obtain a solution containing 0.2 mg/mL of docetaxel (anhydrous).

Sample solution (for Injection labeled as two-vial formulation): Transfer the content of the vial containing the Injection concentrate to a suitable volumetric flask. Dissolve in an amount of alcohol equivalent to 5% of the final volume, and dilute with *Diluent* to volume to obtain a solution having a concentration of 0.2 mg/mL of docetaxel (anhydrous).

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

Mode: LC

Detector: UV 232 nm. For *Identification B*, use a diode array detector.

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

Temperatures

Refrigerated autosampler: 10°

Column: 45°

Flow rate: 1.2 mL/min

Injection volume: 20 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 the labeled amount of docetaxel ($C_{43}H_{53}NO_{14}$) in the portion of Injection taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Mobile phase, Diluent, System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.2 μg/mL of [USP Docetaxel RS](#) in *Diluent* from the *Standard solution*

System suitability

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

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 Injection taken:

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

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

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

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

Acceptance criteria: See [Table 2](#). Disregard any impurity peak less than 0.1% and any peak with a relative retention time less than 0.2 or greater than 1.3.

Table 2