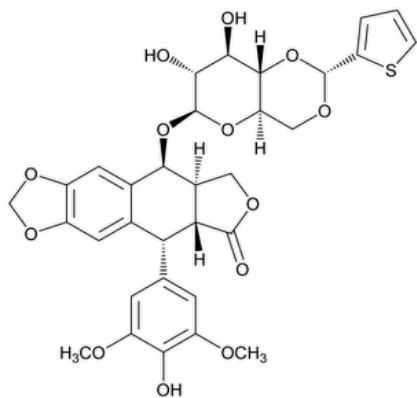


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# Teniposide



$C_{32}H_{32}O_{13}S$  656.65  
Furo[3',4':6,7]naphtho[2,3-d]-1,3-dioxol-6(5aH)-one, 5,8,8a,9-tetrahydro-5-(4-hydroxy-3,5-dimethoxyphenyl)-9-[4,6-O-(2-thienylmethylene)-β-D-glucopyranosyloxy]-, [5R-[5α,5aβ,8aα,9β(R\*)]]-;  
4'-Demethylepipodophyllotoxin 9-[4,6-O-(R)-2-thienylidene-β-D-glucopyranoside];  
(5S,5aR,8aR,9R)-9-(4-Hydroxy-3,5-dimethoxyphenyl)-8-oxo-5,5a,6,8,8a,9-hexahydrofuro[3',4':6,7]naphtho[2,3-d][1,3]dioxol-5-yl 4,6-O-(thiophen-2-ylmethylidene)-β-D-glucopyranoside CAS RN®: 29767-20-2; UNII: 957E6438QA.

**DEFINITION**  
Teniposide contains NLT 97.0% and NMT 103.0% of teniposide ( $C_{32}H_{32}O_{13}S$ ), calculated on the anhydrous and solvent-free basis.

[**CAUTION**—Great care should be taken in handling teniposide, because it is a cytotoxic agent.]

**IDENTIFICATION**  
*Change to read:*

- **A.** **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**▲ (CN 1-MAY-2020)
- **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**  
**Buffer:** 5 mM monobasic potassium phosphate in water  
**Solution A:** Acetonitrile and *Buffer* (36:64). Adjust with dibasic potassium phosphate to an apparent pH of 7.0.  
**Solution B:** Acetonitrile and water (90:10)  
**Mobile phase:** See [Table 1](#). Return to original conditions and re-equilibrate the system for 15 min.

Table 1

| Time (min) | Solution A (%) | Solution B (%) |
|------------|----------------|----------------|
| 0          | 100            | 0              |
| 25         | 100            | 0              |
| 60         | 0              | 100            |

| Time<br>(min)   | Solution A<br>(%) | Solution B<br>(%) |
|-----------------|-------------------|-------------------|
| 66 <sup>a</sup> | 0                 | 100               |

<sup>a</sup> This time may be adjusted if needed to be at least 2.2 times the retention time of the teniposide peak.

**Diluent:** Acetonitrile and *Buffer* (1:1)

**Standard solution:** 0.4 mg/mL of [USP Teniposide RS](#), prepared as follows. Transfer [USP Teniposide RS](#) to a suitable volumetric flask, add acetonitrile equivalent to 10% of the final volume, and sonicate to dissolve. Dilute with *Diluent* to volume.

**Sample solution:** 0.4 mg/mL of Teniposide, prepared as follows. Transfer Teniposide to a suitable volumetric flask, add acetonitrile equivalent to 10% of the final volume, and sonicate to dissolve. Dilute with *Diluent* to volume.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 220 nm

**Column:** 4.6-mm × 25-cm; 4-μm packing L11

**Flow rate:** 1 mL/min

**Injection volume:** 10 μL

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Relative standard deviation:** NMT 0.85%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of teniposide ( $C_{32}H_{32}O_{13}S$ ) in the portion of Teniposide 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 Teniposide RS](#) in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** 97.0%–103.0% on the anhydrous and solvent-free basis

#### IMPURITIES

##### • [RESIDUE ON IGNITION \(281\)](#)

**Analysis:** Ignite the sample at 700°–800°.

**Acceptance criteria:** NMT 0.2%

##### • ORGANIC IMPURITIES

**Solution A, Solution B, Mobile phase, Diluent, and Sample solution:** Proceed as directed in the Assay.

**System suitability solution:** Use the *Standard solution* in the Assay. [NOTE—[USP Teniposide RS](#) contains a small amount of *R*-3-thienylidene regioisomer.]

**Chromatographic system:** Proceed as directed in the Assay, except for *Detectors*.

#### Detectors

**UV 242 nm:** For thiophenealdehyde

**UV 220 nm:** For all other impurities

#### System suitability

**Sample:** *System suitability solution*

#### Suitability requirements

**Resolution:** NLT 1.0 between *R*-3-thienylidene regioisomer and teniposide peaks

#### Analysis

**Sample:** *Sample solution*

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