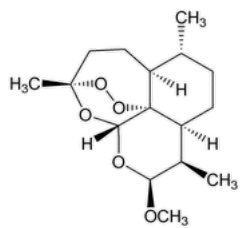


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Add the following:

▲Artemether



$C_{16}H_{26}O_5$ 298.37
3,12-Epoxy-12*H*-pyrano[4,3-*j*]-1,2-benzodioxepin, decahydro-10-methoxy-3,6,9-trimethyl-, (3*R*,5*aS*,6*R*,8*aS*,9*R*,10*S*,12*R*,12*aR*); (3*R*,5*aS*,6*R*,8*aS*,9*R*,10*S*,12*R*,12*aR*)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12*H*-pyrano[4,3-*j*]-1,2-benzodioxepin CAS RN[®]: 71963-77-4; UNII: C7D6T3H22J.

DEFINITION
Artemether contains NLT 98.0% and NMT 102.0% of artemether ($C_{16}H_{26}O_5$).

- 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**
Protect all solutions containing artemether from light.
Solution A: [Acetonitrile](#) and [water](#) (200:800)
Solution B: [Acetonitrile](#) and [water](#) (800:200)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
2	100	0
3	40	60
14	0	100
15.5	0	100
15.6	100	0
18	100	0

Diluent: [Acetonitrile](#) and [water](#) (50:50)
Standard solution: 0.5 mg/mL of [USP Artemether RS](#) in *Diluent*. Sonicate to dissolve if necessary.
Sample solution: 0.5 mg/mL of Artemether in *Diluent*. Sonicate to dissolve if necessary.
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: LC

Detector: UV 210 nm**Column:** 4.6-mm × 15-cm; 1.8-μm packing [L1](#)**Temperatures****Autosampler:** 5°**Column:** 30°**Flow rate:** 0.8 mL/min**Injection volume:** 50 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of artemether (C₁₆H₂₆O₅) in the portion of Artemether taken:

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

 r_U = peak response of artemether from the *Sample solution* r_S = peak response of artemether from the *Standard solution* C_S = concentration of [USP Artemether RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Artemether in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0%**IMPURITIES**• **RESIDUE ON IGNITION (281):** NMT 0.1%• **ORGANIC IMPURITIES**

Protect all solutions containing artemether from light.

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.**Sensitivity solution:** 5 μg/mL of [USP Artemether RS](#) in *Diluent*. Sonicate to dissolve if necessary.**Standard solution:** 0.02 mg/mL of [USP Artemether RS](#) in *Diluent*. Sonicate to dissolve if necessary.**Sample solution:** 10 mg/mL of Artemether in *Diluent*. Sonicate to dissolve if necessary.**System suitability****Samples:** *Sensitivity solution* and *Standard solution***Suitability requirements****Relative standard deviation:** NMT 5%, *Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

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

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

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of artemether from the *Standard solution* C_S = concentration of [USP Artemether RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Artemether in the *Sample solution* (mg/mL) F = relative response factor (see [Table 2](#))**Acceptance criteria:** See [Table 2](#). The reporting threshold is 0.05%.**Table 2**