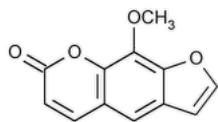


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Methoxsalen



$C_{12}H_8O_4$ 216.19

7H-Furo[3,2-g][1]benzopyran-7-one, 9-methoxy-;

9-Methoxy-7H-furo[3,2-g][1]benzopyran-7-one;

9-Methoxy-7H-furo[3,2-g]chromen-7-one CAS RN®: 298-81-7.

DEFINITION

Methoxsalen contains NLT 98.0% and NMT 102.0% of methoxsalen ($C_{12}H_8O_4$), calculated on the anhydrous basis.

[CAUTION—Avoid contact with the skin.]

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 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

Mobile phase: [Acetonitrile](#) and [water](#) (35:65)

Standard stock solution: 0.2 mg/mL of [USP Methoxsalen RS](#) in [alcohol](#)

Standard solution: 4 µg/mL of [USP Methoxsalen RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: 0.2 mg/mL of Methoxsalen in [alcohol](#)

Sample solution: 4 µg/mL of Methoxsalen in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing [L1](#); or 3.9-mm × 30-cm; 10-µm packing [L1](#); or 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 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 methoxsalen ($C_{12}H_8O_4$) in the portion of Methoxsalen taken:

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

r_U = peak response of methoxsalen from the *Sample solution*

r_S = peak response of methoxsalen from the *Standard solution*

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

C_U = concentration of Methoxsalen in the *Sample solution* (µg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION (281).**

Sample: 1 g

Acceptance criteria: NMT 0.1%

• **ORGANIC IMPURITIES**

Solution A: 6% tetrahydrofuran in [water](#)

Solution B: [Methanol](#)

Solution C: *Solution A* and [methanol](#) (60:40)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	0	0	100
21.00	0	0	100
21.01	60	40	0
40.00	35	65	0
45.00	60	40	0
45.01	0	0	100
50.00	0	0	100

Diluent: [Acetonitrile](#) and [water](#) (1:1)

System suitability solution: 0.05 mg/mL each of [USP Methoxsalen Related Compound A RS](#) and [USP Methoxsalen Related Compound B RS](#) in *Diluent*

Standard stock solution: 1.0 mg/mL of [USP Methoxsalen RS](#) in *Diluent*

Standard solution: 1.0 µg/mL of [USP Methoxsalen RS](#) in *Diluent* from the *Standard stock solution*

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

Sample solution: 1.0 mg/mL of Methoxsalen in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 247 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L11](#)

Flow rate: 1.2 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.0 between methoxsalen related compound A and methoxsalen related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0%, *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 Methoxsalen taken:

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

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

r_S = peak area of methoxsalen from the *Standard solution*

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

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