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Methoxsalen Topical Solution

DEFINITION

Change to read:

Methoxsalen Topical Solution is a solution of methoxsalen in a suitable vehicle. ▲It contains NLT 92.0% and NMT 108.0% of the labeled amount of methoxsalen ($C_{12}H_8O_4$).▲ (USP 1-May-2019)

IDENTIFICATION

Change to read:

• **A.** ▲▲**Spectroscopic Identification Tests** ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020) ▲ (USP 1-May-2019)

Sample solution: Nominally equivalent to 8 µg/mL of methoxsalen in alcohol, from Topical Solution

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of a similar solution of USP Methoxsalen RS, concomitantly measured.

▲[Note—The UV spectra of the major peaks of the *Sample solution* and the *Standard solution* as obtained in the *Assay* may also be used to meet the *Acceptance criteria*.]▲ (USP 1-May-2019)

Add the following:

▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2019)

ASSAY

Change to read:

• **Procedure**

Mobile phase: Acetonitrile and water (35:65)

▲▲ (USP 1-May-2019)

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*▲ (USP 1-May-2019)

Sample stock solution: Nominally 0.2 mg/mL of methoxsalen in alcohol prepared as follows. Transfer a volume of Topical Solution nominally equivalent to 20 mg of methoxsalen to a 100-mL volumetric flask and dilute with alcohol to volume.

Sample solution: Nominally equivalent to 4 µg/mL of methoxsalen as follows. Transfer 2.0 mL of *Sample stock solution*▲▲ (USP 1-May-2019) to a 100-mL volumetric flask. Dilute with *Mobile phase* to volume. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 254 nm. ▲For *Identification A*, use a diode array detector set at 200–400 nm.▲ (USP 1-May-2019)

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▲ (USP 1-May-2019)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

▲▲ (USP 1-May-2019)

Suitability requirements

▲**Tailing factor:** NMT 2.0▲ (USP 1-May-2019)

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of methoxsalen ($C_{12}H_8O_4$) in the portion of Topical Solution taken:

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 Methoxsalen RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of methoxsalen in the *Sample solution* (µg/mL)▲ (USP 1-May-2019)

Acceptance criteria: ▲92.0%–108.0%▲ (USP 1-May-2019)

OTHER COMPONENTS

• **Alcohol Determination ⟨611⟩** (if present)**:** 66.5%–77.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Methoxsalen RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METHOXSALEN TOPICAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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