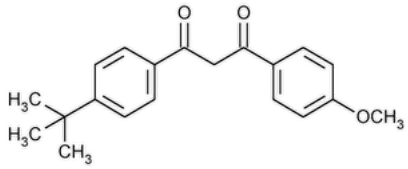
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: USP Monographs
DocId: GUID-17444D19-6F52-4722-AC09-E667C2F3FEB4_3_en-US
DOI: https://doi.org/10.31003/USPNF_M6560_03_01
DOI Ref: htb4a

Avobenzone



$C_{20}H_{22}O_3$ 310.40

1,3-Propanedione, 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)-;

1-(*p*-*tert*-Butylphenyl)-3-(*p*-methoxyphenyl)-1,3-propanedione CAS RN®: 70356-09-1; UNII: G63QQF2NOX.

DEFINITION

Avobenzone contains NLT 95.0% and NMT 105.0% of avobenzone ($C_{20}H_{22}O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K** ▲or ⟨197A⟩▲ (USP 1-Aug-2020)

Change to read:

• **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-Aug-2020)

ASSAY

Change to read:

• **Procedure**

Standard solution: 50 mg/mL of USP Avobenzone RS in acetone

Sample solution: 50 mg/mL of Avobenzone in acetone

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 25-m fused silica capillary; coated with ▲a 0.25-µm layer of▲ (USP 1-Aug-2020) phase G1

Temperatures

Injection port: 200°

Detector: 280°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
200	4	280	—

Carrier gas: Helium

▲**Flow rate:** 2 mL/min▲ (USP 1-Aug-2020)

Injection volume: 1 µL

Injection type: Split, split ratio 50:1

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of avobenzone ($C_{20}H_{22}O_3$) in the portion of Avobenzone taken:

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

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

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

C_S = concentration of USP Avobenzone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity in the portion of Avobenzone taken:

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

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

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

Acceptance criteria

Any unspecified impurity: NMT 3.0%

Total impurities: NMT 4.5%

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry under vacuum at 70° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Avobenzone RS

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

Topic/Question	Contact	Expert Committee
AVOBENZONE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(2)

Current DocID: GUID-17444D19-6F52-4722-AC09-E667C2F3FEB4_3_en-US

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