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Simethicone Oral Suspension

DEFINITION

Simethicone Oral Suspension is a suspension of Simethicone in Water. It contains an amount of polydimethylsiloxane ($[-(CH_3)_2\ SiO-]_n$) that is NLT 85.0% and NMT 115.0% of the labeled amount of simethicone.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩**,** *Infrared Spectroscopy*: **197S**▲ (CN 1-May-2020)

Standard solution, Sample solution, and **Blank:** Prepare as directed in the *Assay*.

Cell: 0.5 mm

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Standard solution: 2.4 mg/mL of USP Polydimethylsiloxane RS, prepared as follows. Transfer 60 mg of USP Polydimethylsiloxane RS to a 25-mL volumetric flask, add 15 mL of hexanes, and sonicate for 3 min. Allow to cool, dilute with hexanes to volume, and mix. Transfer 10 mL of this solution to a capped test tube, add 1 g of anhydrous sodium sulfate, mix for about 1 min, centrifuge, and use the clear supernatant.

Sample solution: Transfer an quantity of Oral Suspension, equivalent to about 240 mg of simethicone, to a glass-stoppered centrifuge tube. Add 5 mL of methanol, and mix for about 15 s. Add 30.0 mL of hexanes, and mix for about 10 s. Loosen the stopper, and heat the tube for about 10 min in a water bath at 65° ± 1°. Mix for 1 min, and centrifuge. Using a glass syringe, transfer the upper hexanes layer to a 100-mL volumetric flask. Repeat the extraction with two 30.0-mL portions of hexanes, combining the hexanes extracts in the 100-mL volumetric flask. If an emulsion forms during any of the extractions, as much as 2 mL of methanol may be added to disperse the emulsion. Allow the combined extracts to cool, dilute with hexanes to volume, and mix. Transfer 10 mL of this solution to a capped test tube, add 1 g of anhydrous sodium sulfate, mix for 1 min, centrifuge, and use the clear supernatant.

Blank: Mix 100 mL of hexanes and 10 g of anhydrous sodium sulfate, allow to settle, centrifuge, and use the clear supernatant.

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solution* and the *Sample solution* at the wavelength of maximum absorbance at about 7.9 µm, with a suitable IR spectrophotometer, using the *Blank* to set the instrument.

Calculate the percentage of polydimethylsiloxane ($[-(CH_3)_2\ SiO-]_n$) in the portion of the Oral Suspension taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 85.0%–115.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.5–4.6

ADDITIONAL REQUIREMENTS

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

- **USP Reference Standards ⟨11⟩**
  USP Polydimethylsiloxane RS

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

Topic/Question	Contact	Expert Committee
SIMETHICONE ORAL SUSPENSION	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

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