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Simethicone Emulsion

DEFINITION

Simethicone Emulsion is a water-dispersible form of Simethicone composed of Simethicone, suitable emulsifiers, preservatives, and water. It may contain suitable viscosity-increasing agents. It contains an amount of polydimethylsiloxane $[(\text{CH}_3)_2\text{SiO}]_n$ that is NLT 85.0% and NMT 110.0% of the labeled amount of simethicone.

IDENTIFICATION

Change to read:

- ▲ **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy** ▲ (CN 1-MAY-2020)

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

Analysis: Place a suitable amount of the *Sample solution* in a suitable container, and dry it with a stream of nitrogen or other appropriate means to evaporate the solvent. Similarly proceed with the *Standard solution*. Record the spectra of the residues using (197A) or (197E), and examine the spectra in the range between 1400 cm^{-1} and 700 cm^{-1} .

Acceptance criteria

For spectra obtained using (197A): The spectrum from the *Sample solution* shows strong bands at $1260 \pm 10\text{ cm}^{-1}$, $1015 \pm 15\text{ cm}^{-1}$, and $795 \pm 15\text{ cm}^{-1}$, and a broad shoulder at $1085 \pm 15\text{ cm}^{-1}$, similar to the spectrum from the *Standard solution*. [NOTE—The exact maxima of the broad shoulder near 1085 cm^{-1} may differ by up to 15 cm^{-1} for the spectra from the *Sample solution* and the *Standard solution*.]

For spectra obtained using (197E): The spectrum from the *Sample solution* shows a strong band at $1260 \pm 10\text{ cm}^{-1}$ and partially resolved bands near $1095 \pm 15\text{ cm}^{-1}$, $1020 \pm 15\text{ cm}^{-1}$, and $800 \pm 15\text{ cm}^{-1}$, similar to the spectrum from the *Standard solution*.

ASSAY

PROCEDURE

Use glass apparatus only; avoid use of plasticware. Proper mixing of the Emulsion before sampling and testing is crucial.

Standard solution: 2 mg/mL of [USP Polydimethylsiloxane RS](#) in toluene. Treat a 25.0-mL aliquot of this solution in the same manner as the *Blank*, beginning with “add 50 mL of dilute hydrochloric acid (2 in 5)...”.

Sample: Equivalent to 50 mg of simethicone from the Emulsion

Sample solution: To the *Sample* add 25.0 mL of toluene. Treat in the same manner as the *Blank*, beginning with “add 50 mL of dilute hydrochloric acid (2 in 5)...”.

Instrumental conditions

(See [Mid-Infrared Spectroscopy \(854\)](#).)

Mode: Infrared

Cell: 0.5 mm

Analytical wavelength: Maximum absorbance at about $7.9\text{ }\mu\text{m}$ (1259 cm^{-1})

Blank: To 25.0 mL of toluene add 50 mL of dilute hydrochloric acid (2 in 5), close the bottle securely with a cap having an inert liner, vigorously shake by hand for 5 s, then shake for 5–20 min on a suitable shaker. [NOTE—The following shakers were found suitable: (1) a reciprocating shaker at a rate of about 200 oscillations/min and a stroke of $38 \pm 2\text{ mm}$ or (2) a wrist-action shaker with a radius of $13.3 \pm 0.4\text{ cm}$ (measured from center of shaft to center of bottle) that uses an arc of 10° at a frequency of $300 \pm 30\text{ strokes/min}$. The recommended shaking time is about 20 min, which can be adjusted as needed.] Centrifuge the mixture. [NOTE—The following centrifuging condition was found suitable: $1500 \times g$ for 30–40 min.] Remove from the centrifuge, and immediately transfer about 5 mL of the upper organic (toluene) layer to a 15-mL screw-capped test tube containing about 1 g of anhydrous sodium sulfate. Close the tube with a screw-cap having an inert liner, agitate vigorously, and centrifuge the mixture until a clear supernatant is obtained. [NOTE—The following centrifuging condition was found suitable: $1500 \times g$ for about 10 min.]

Analysis

[NOTE—Wash the cell with copious amounts of toluene to ensure that there is no carryover or residue.]

Samples: *Standard solution, Sample solution, and Blank*

Calculate the percentage of polydimethylsiloxane ($[-(\text{CH}_3)_2\text{SiO}-]_n$) in the labeled amount of simethicone in the Emulsion:

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

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%–110.0%

SPECIFIC TESTS

• **MICROBIAL ENUMERATION TESTS** (61): The total aerobic microbial count does not exceed 10^2 cfu/g.

• **DEFOAMING ACTIVITY**

Foaming solution: 10 mg/mL of octoxynol 9 in water

Sample solution: Transfer a quantity of Emulsion, equivalent to 300 mg of simethicone, to a 60-mL bottle. Dilute with water to 30 g, cap the bottle, and shake vigorously.

Analysis

[NOTE—For each test, use a clean, unused, 250-mL glass jar.]

Add, dropwise, 500 μL of the *Sample solution* to a clean, unused, cylindrical 250-mL glass jar, fitted with a 50-mm cap and containing 100 mL of the *Foaming solution*. Cap the jar, and clamp it in an upright position on a wrist-action shaker. Using a radius of 13.3 ± 0.4 cm (measured from the center of the shaft to the center of the bottle), shake for 10 s through an arc of 10° at a frequency of 300 ± 30 strokes/min. Record the time, in s, required for the foam to collapse. The time for foam collapse is determined at the instant the first portion of foam-free liquid surface appears, measured from the end of the shaking period.

Acceptance criteria: The defoaming activity time does not exceed 15 s.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight 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 EMULSION	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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