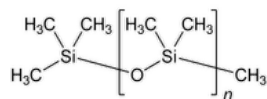


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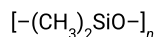
Dimethicone



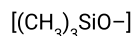
Dimethicone;
 α -(Trimethylsilyl)- ω -methylpoly[oxy(dimethylsilylene)]
 CAS RN[®]: 9006-65-9.

DEFINITION

Dimethicone is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula:



stabilized with trimethylsiloxy end-blocking units of the formula:



wherein n has an average value such that the corresponding nominal viscosity is in a discrete range between 20 and 30,000 centistokes. It contains NLT 97.0% and NMT 103.0% of polydimethylsiloxane $([-(\text{CH}_3)_2\text{SiO}-]_n)$.

The requirements for viscosity, specific gravity, refractive index, and loss on heating differ for the several types of Dimethicone, as set forth in [Table 1](#).

IDENTIFICATION

- **A.** The IR absorption spectrum of the *Sample* exhibits maxima only at the same wavelengths as that of the *Standard*, obtained as directed in the Assay.

ASSAY

• PROCEDURE

Standard: [USP Polydimethylsiloxane RS](#)

Sample: Dimethicone

Instrumental conditions

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

Mode: IR, with a resolution of 4 cm^{-1} and fitted with an accessory for attenuated total reflectance and a germanium (Ge) sample trough (45° or 60°)

Wavelength range: 4000 to 700 cm^{-1}

Analysis

Samples: *Standard* and *Sample*

Using an empty and clean trough, determine the background spectrum. Fill the trough with the *Sample*, and record the spectrum. Clean the trough, fill it with the *Standard*, and determine the spectrum. Examine the spectra in the range between 1300 and 1200 cm^{-1} , and determine the absorbance of the peak in each spectrum at about 1259 cm^{-1} .

Calculate the percentage of polydimethylsiloxane $([-(\text{CH}_3)_2\text{SiO}-]_n)$ in the Dimethicone taken:

$$\text{Result} = (A_U/A_S) \times (D_S/D_U) \times 100$$

A_U = absorbance of the *Sample*

A_s = absorbance of the *Standard*

D_s = specific gravity of [USP Polydimethylsiloxane RS](#)

D_u = specific gravity of Dimethicone

Acceptance criteria: 97.0%–103.0%

SPECIFIC TESTS

• **SPECIFIC GRAVITY (841):** See [Table 1](#).

• **REFRACTIVE INDEX (831):** See [Table 1](#).

• ACIDITY

Sample: 15.0 g

Analysis: Dissolve the *Sample* in a mixture of 15 mL of toluene and 15 mL of butyl alcohol, previously neutralized to bromophenol blue TS, and titrate with 0.050 N alcoholic potassium hydroxide to a bromophenol blue endpoint.

Acceptance criteria: NMT 0.10 mL of 0.050 N alcoholic potassium hydroxide is required.

• LOSS ON HEATING

Sample: 1 g

Analysis: Preheat an open aluminum vessel (60 mm in diameter and 10 mm high) at 150° for 30 min, and allow to cool to room temperature. Tare the vessel, transfer the *Sample* to it, heat at 150° in a circulating air oven for 2 h, and allow to come to room temperature in a desiccator before weighing.

Acceptance criteria: See [Table 1](#).

Table 1

Nominal Viscosity (centistokes)	Viscosity (centistokes)		Specific Gravity		Refractive Index		Loss on Heating (%)
	Min.	Max.	Min.	Max.	Min.	Max.	Max.
20	18	22	0.946	0.954	1.3980	1.4020	20.0
50	47.5	52.5	0.955	0.965	1.4005	1.4045	2.0
100	95	105	0.962	0.970	1.4005	1.4045	0.3
200	190	220	0.964	0.972	1.4013	1.4053	0.3
350	332.5	367.5	0.965	0.973	1.4013	1.4053	0.3
500	475	525	0.967	0.975	1.4013	1.4053	0.3
1000	950	1050	0.967	0.975	1.4013	1.4053	0.3
12,500	11,875	13,125	—	—	1.4015	1.4055	2.0
30,000	27,000	33,000	0.969	0.977	1.4010	1.4100	2.0

• **BACTERIAL ENDOTOXINS TEST (85):** (where it is intended for use in coating containers that come in contact with articles for parenteral use)

Sample: 1.0 mL

Analysis: Mix the *Sample* with 4.0 mL of polydimethylsiloxane having a viscosity of 0.65 centistokes, previously tested and shown to be negative for bacterial endotoxins, by mixing on a vortex mixer for 1 min in an extraction tube. Add 10 mL of water, and mix on a vortex mixer for NLT 60 min. Allow the layers to separate, and use the lower aqueous layer as the sample.

Acceptance criteria: It contains NMT 1.0 USP Endotoxin Unit/mL, equivalent to NMT 10 Endotoxin Units/mL of the Dimethicone taken.

• **VISCOSITY—CAPILLARY METHODS (911)**, and **VISCOSITY—ROTATIONAL METHODS (912)**.

Analysis: Determine the viscosity of Dimethicone having a nominal viscosity of less than 1000 centistokes at 25 ± 0.1°, using a capillary viscometer. Determine the viscosity of Dimethicone having a nominal viscosity of 1000 centistokes or greater at 25 ± 0.1°, using a rotational viscometer.

Acceptance criteria: See [Table 1](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label it to indicate its nominal viscosity value. Dimethicone intended for use in coating containers that come in contact with articles for parenteral use is so labeled.
- **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
DIMETHICONE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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