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# Simethicone Tablets

» Simethicone Tablets contain an amount of polydimethylsiloxane ( $[-(\text{CH}_3)_2\text{SiO}-]_n$ ) that is not less than 85.0 percent and not more than 115.0 percent of the labeled amount of simethicone.

**Packaging and storage**—Preserve in well-closed containers.

**Labeling**—Tablets that are gelatin-coated are so labeled.

**USP REFERENCE STANDARDS** (11).—  
[USP Polydimethylsiloxane RS](#)

**Change to read:**

**Identification,**▲[Spectroscopic Identification Tests \(197\)](#),[Infrared Spectroscopy: 197S](#)▲ (CN 1-May-2020)

[NOTE—Use the procedural blank, prepared as directed in the Assay, to set the instrument.]

*Test solution*—Prepare as directed for the Assay preparation in the Assay.

*Standard solution*—Prepare as directed for the Standard preparation in the Assay.

*Cell size:* 0.5 mm.

**DISINTEGRATION** (701): 30 minutes in water; 60 minutes in water for plain-coated Tablets; and 45 minutes in simulated gastric fluid for Tablets labeled as gelatin-coated.

**UNIFORMITY OF DOSAGE UNITS** (905): meet the requirements.

**Assay**—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of simethicone, to a round, narrow-mouth, screw-capped, 120-mL bottle, and proceed as directed in the Assay under [Simethicone](#), beginning with “add 25.0 mL of toluene,” except that for Tablets labeled as gelatin-coated, shake for 30 minutes instead of 5 minutes. Calculate the quantity, in mg, of  $[-(\text{CH}_3)_2\text{SiO}-]_n$  in the portion of Tablets taken by the formula:

$$25C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of [USP Polydimethylsiloxane RS](#) in the Standard solution, and  $A_U$  and  $A_S$  are the absorbances of the solution from the Tablets and the Standard solution, respectively.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SIMETHICONE TABLETS	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

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