Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-607165D3-3F7C-4AFF-B37C-70A7168413E0_2_en-US
DOI: https://doi.org/10.31003/USPNF_M75405_02_01
DOI Ref: bdl2x

Simethicone Capsules

DEFINITION

Simethicone Capsules contain 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: Meet the requirements

ASSAY

• **Procedure**

Perform this procedure on at least 3 individual Capsules. The mean of the assay values obtained is the assay value.

Standard solution: Prepare similarly to the *Sample solution*, except use 2.5 mg/mL of USP Polydimethylsiloxane RS in toluene.

Sample solution: Transfer 1 Capsule to a round, narrow-mouth, screw-capped, 120-mL bottle. Add 20 mL of 6 N hydrochloric acid, and allow to stand, with frequent swirling, until the Capsule has dissolved. Add 10.0 mL of toluene for each 25 mg of the labeled amount of simethicone in the Capsule, close the bottle securely with a cap having an inert liner, and shake by mechanical means for 5 min. Allow the phases to separate, draw off 10 mL of the upper organic (toluene) layer to a test tube containing 0.5 g of anhydrous sodium sulfate, agitate vigorously for 30 s, and allow the mixture to settle. If necessary, centrifuge the mixture to obtain a clear solution.

Blank: Prepare similarly to the *Sample solution*, except use 10 mL of toluene.

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solution* and the *Sample solution* in 0.5-mm cells 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 Capsule taken:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

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)

V = volume of toluene used to prepare the *Sample solution* (mL)

L = labeled amount of simethicone (mg/Capsule)

Acceptance criteria: 85.0%–115.0%

PERFORMANCE TESTS

• **Disintegration** ⟨701⟩

For hard gelatin capsules

Time: 30 min, determined using water

For soft gelatin capsules

Time: 30 min, determined using 1.0% octoxynol-9 (w/w) in water, using disks

Acceptance criteria: Meet the requirements

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed 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 CAPSULES	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. PF 33(5)

Current DocID: GUID-607165D3-3F7C-4AFF-B37C-70A7168413E0_2_en-US

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