



Edition: BP 2025 (Ph. Eur. 11.6 update)

Simeticone for Oral Use

[General Notices](#)

Action and use

Silicon dioxide analogue; defoaming agent.

Preparations

[Simeticone Suspension for Infants](#)

When activated dimethicone is prescribed or demanded, Simeticone for Oral Use shall be dispensed or supplied.

DEFINITION

Simeticone for Oral Use contains not less than 4.5% and not more than 8.0% w/w of silica, SiO₂, and not less than 91.0% and not more than 97.0% w/w of Dimeticone 1000. It is prepared by the addition of finely powdered silica to Dimeticone 1000.

CHARACTERISTICS

A viscous, grey, translucent liquid.

Immiscible with [water](#) and with [ethanol \(96%\)](#); almost completely soluble in [toluene](#), leaving a residue of silica.

IDENTIFICATION

A. The [infrared absorption spectrum](#) of the supernatant liquid obtained by centrifugation, [Appendix II A](#), is concordant with the *reference spectrum* of dimeticone ([RS 381](#)).

B. Ignite; dense white fumes are evolved leaving a white residue which is insoluble in [hydrochloric acid](#).

TESTS

Acidity

Dissolve 15.0 g in a mixture of 15 mL of [toluene](#) and 15 mL of [butan-1-ol](#), previously neutralised to a 0.5% w/v solution of [bromophenol blue](#) in [ethanol \(96%\)](#), and titrate with [0.1 M ethanolic potassium hydroxide VS](#) using the bromophenol blue solution as indicator. Not more than 0.15 mL is required to change the colour of the solution.

[Refractive index](#)

Of the supernatant liquid obtained in Identification test A, 1.4050 to 1.4080, [Appendix V E](#).

[Viscosity](#)

Of the supernatant liquid obtained in Identification test A, 950 to 1050 mm² s⁻¹, [Appendix V.H](#), Method I, using a U-tube viscometer (size G).

Weight per mL

Of the supernatant liquid obtained in Identification test A, 0.965 to 0.980 g, [Appendix V.G](#).

ASSAY

For silica

To 1 g add 50 mL of [toluene](#), mix well and filter through an ignited silica crucible. Wash the residue thoroughly with [toluene](#), dry at 105° and ignite to constant weight at 500°.

For dimeticone

Place 40 mg in a stoppered centrifuge tube, add 20 mL of [toluene](#) and shake for 20 minutes. Filter and record the [infrared absorption spectrum](#), [Appendix II.A](#), of a 0.5-mm layer of the filtrate over the range 1330 to 1180 cm⁻¹ (7.52 to 8.47 μm). Measure the absorbance of the CH₃Si stretching band at the maximum at 1261 cm⁻¹ (7.93 μm). Repeat the operation using [dimeticone EPCRS](#) in place of the preparation being examined.