



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

## Simeticone Suspension for Infants

### [General Notices](#)

#### Action and use

Silicon dioxide analogue; defoaming agent.

### DEFINITION

Simeticone Suspension for Infants is a suspension of Simeticone for Oral Use in a suitable flavoured aqueous vehicle.

*The suspension complies with the requirements stated under Oral Liquids and with the following requirements.*

#### Content of dimeticone

90.0 to 110.0% of the stated amount.

### IDENTIFICATION

The [infrared absorption spectrum, Appendix II A](#), of the sample solution prepared in the Assay is concordant with that obtained for the solution of [dimeticone EPCRS](#). Disregard the region of the spectrum from  $850\text{ cm}^{-1}$  to  $750\text{ cm}^{-1}$ .

### TESTS

#### Acidity

pH, 3.0 to 5.0, [Appendix V L](#).

#### Defoaming activity

Dissolve 1.0 g of [octoxinol 10](#) in sufficient [water](#) to produce 100 mL (foaming solution). To a weighed quantity of the suspension containing 0.3 g of dimeticone add sufficient [water](#) to produce 30 g and mix thoroughly (test solution). Into a suitable container introduce 100 mL of the foaming solution and 0.5 mL of the test solution. Close tightly and shake the mixture for 10 seconds at 300 oscillations per minute, at an angle of oscillation of about  $\pm 10^\circ$  and an oscillation radius of about 13 cm. The time between the end of the shaking and the instant the first portion of foam-free liquid surface appears is not greater than 45 seconds.

### ASSAY

Add 25 mL of [toluene](#), pre-washed with 1M [sodium hydroxide](#), and 50 mL of 1M [sodium hydroxide](#) to a quantity of the suspension containing 50 mg of dimeticone and shake mechanically for 5 minutes. Allow the mixture to stand for 5 minutes, centrifuge the upper layer and dry with [anhydrous sodium sulfate](#). Record the [infrared absorption spectrum, Appendix II A](#), of a 0.5 mm layer of the clear solution over the range  $1375$  to  $1125\text{ cm}^{-1}$  ( $7.27$  to  $8.89\text{ }\mu\text{m}$ ). Measure the

absorbance of the CH<sub>3</sub>Si stretching band at the maximum at 1261 cm<sup>-1</sup> (7.93 μm). Repeat the operation using a 0.2% w/v solution of [dimeticone EPCRS](#) in [toluene](#). Determine the [weight per mL](#) of the suspension, [Appendix V G](#), and calculate the content of dimeticone weight in volume.