

Antifoams and Antifoam Emulsions

To assure consistent quality for use as pharmaceutical ingredients, Dow Corning® brand antifoam products are manufactured, packaged, and tested at the Healthcare Industries Materials Site utilizing principles of GMP guidelines for Active Pharmaceutical Ingredients (APIs).

| Description | Typical Applications | Antifoams | Regulatory Status | | | | | | | Typical Properties† | | | | | | | | | | | | |
|--|---|--|--|---|--|-----------------|----------------------|------------------------------|-------------------------------|---------------------|-------------------------|---------------------|------------|---------------------|-----------------------|--------------|---|---------|-----|-------|-------|---|
| | | | Ph. Eur. (EP) Monograph for Simeticonium | USP Monograph Requirements for Simethicone Emulsion USP | USP Monograph Requirements for Simethicone USP | Technical File¹ | FDA Drug Master File | FDA Regulation 21 CFR 332.10 | FDA Regulation 21 CFR 173.340 | pH | Silicon Dioxide Content | Nonvolatile Content | Volatility | Heavy Metal Content | Defoaming Performance | PDMS Content | % | seconds | ppm | w/w % | w/w % | % |
| Mixture of a low-volatile polydimethylsiloxane fluid and silicon dioxide | <ul style="list-style-type: none"> Foam control in medical and pharmaceutical applications OTC antifatulents | <i>Dow Corning</i> ® Q7-2243 LVA, Simethicone USP | • | • | • | • | • | • | • | 90.5-99 | <15 20 ppm | <5 | <1.0 | | | 4-7 | | | | | | |
| Mixture of polydimethylsiloxane (PDMS) fluid and silicon dioxide | | <i>Dow Corning</i> ® Antifoam M Compound² | • | • | • | • | • | • | • | 90.5-99 | <15 20 ppm | <5 | <1.0 | | | 4-7 | | | | | | |
| Water-dilutable, nonionic emulsion containing 30% low-volatile Simethicone USP by weight | <ul style="list-style-type: none"> Foam control in medical and pharmaceutical applications OTC antifatulents Biofermentation | <i>Dow Corning</i> ® Q7-2587, 30% Simethicone Emulsion USP | • | • | • | • | • | • | • | 30.4 | <15 50 ppm | <5 | | 41.7 | 1.2-2.1 | 2.6 | | | | | | |
| Water-dilutable nonionic emulsion containing 30% Simethicone USP by weight | | <i>Dow Corning</i> ® 7-9245, 30% Simethicone Emulsion USP³ | • | • | • | • | • | • | • | 29.6 | <15 50 ppm | <5 | | >36 | 1.2-2.1 | 2.6 | | | | | | |
| Water-dilutable emulsion containing 30% Simethicone USP by weight and methylcellulose | | <i>Dow Corning</i> ® Medical Antifoam C Emulsion | • | • | • | • | • | • | • | 29.4 | <15 50 ppm | <5 | | 30 | 1.2-2.1 | 2.5 | | | | | | |

† Specifications Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office prior to writing specifications on these products.

¹ Dow Corning can provide Technical Files as needed to meet requirements. In Europe, Dow Corning holds an open Drug Master File for Q7-2243, Q7-2587 and Antifoam M and a Technical File for Medical Antifoam C Emulsion.

² Dow Corning holds a Certificate of Suitability to Simeticone Monograph of the European Pharmacopoeia (Reference number R0-CEP 2004-299-Rev 00 for Simeticone) for this product.

³ This product is available only in the USA.