

DuPont Simethicone Compounds and Simethicone Emulsions for pharmaceutical use

	Dow Corning™ Antifoam M Compound	Dow Corning™ Q7-2243 LVA Simethicone USP	Dow Corning™ Medical Antifoam A Compound	Dow Corning™ Q7-2587 30% Simethicone Emulsion USP	Dow Corning™ 7-9255 30% Simethicone Emulsion USP	Dow Corning™ Medical Antifoam C Emulsion USP
Characteristics & Properties						
Description	Simethicone Compound	Simethicone Compound	Simethicone Compound	Simethicone Emulsion	Simethicone Emulsion	Simethicone Emulsion
Pharmacopoeial grade	Simeticone PhEur	Simethicone USP/PhEur	Simethicone USP	Simethicone USP ¹	Simethicone Emulsion USP ¹	Simethicone Emulsion USP ¹
API	Yes (PhEur)	Yes (PhEur)	No	Yes (USP, historical use in Europe ²)	Yes (USP)	No
Processing aid	Yes	Yes	Yes	Yes	Yes	Yes
Kosher certified	Yes	Yes	Yes	Yes	Yes	Yes
Halal certified	No	Yes	No	Yes	No	Yes
Appearance	Light grey liquid	Light grey liquid	Grey liquid	Off white liquid	Off white liquid	Off white liquid
Based on vegetable surfactant	N/A	N/A	N/A	Yes	Yes	Yes
Viscosity³	3100 cP	570 cP	500 cP	31500 cP	134000 cP	1500 cP
Simethicone level	100%	100%	100%	30%	30%	30%
PDMS level	90.5-99.0%	90.5-99.0%	90.5-99.0%	28.0-32.0%	27.8-31.6%	27.0-33.0%
Loss on heating (Volatiles)	≤1%	≤1%	≤ 18%	N/A	N/A	N/A
Defoaming	< 15 sec	< 15 sec	< 15 sec	< 15 sec	< 15 sec	< 15 sec
Heavy metals⁴	< 5 ppm	< 5 ppm	< 5 ppm	< 5 ppm	< 5 ppm	< 5 ppm
Shelf life	18 months	24 months	36 months	36 months	24 months	48 months
Regulatory						
Certificate of Suitability (CEP)	Yes	Yes	No	N/A	N/A	N/A
US Drug Master File	No	Yes	Yes	Yes	No ⁵	Yes
GMP produced per ICH Q7 principles	Yes	Yes	Yes	Yes	Yes	Yes
FDA 21 CFR 332.10⁶	Yes	Yes	Yes	Yes	Yes	Yes
FDA 21 CFR 173.340⁷	Yes	Yes	Yes	Yes	Yes	Yes

¹ No Simethicone Emulsion monograph currently exists in the PhEur

² Proven historical use/registration on the European market (although no PhEur monograph exists)

³ Viscosity measurement data depend on specific testing conditions (available upon request)

⁴ Elemental impurities data available upon request

⁵ Intended to be completed in 2015

⁶ Antiflatulent active ingredients

⁷ Defoaming agents

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