



RioCare India Private Limited

Plot No. R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, District: Thane,
Maharashtra, INDIA

FINISHED PRODUCT SPECIFICATION

Simethicone Emulsion (Simul-73)	Effective Date : 22/06/2022	Reference
Specification No.: SPEC-SML-01-08	Supersedes doc. : 01/04/2022	USP-NF 2022, Issue 1

NAME : Simethicone Emulsion USP- 30%.

DEFINITION : Simethicone Emulsion is a water dispersible form of Simethicone composed of Simethicone, suitable emulsifiers, preservatives and water. It may contain suitable viscosity-increasing agents. It contains an amount of Polydimethylsiloxane $[-(\text{CH}_3)_2\text{SiO-}]_n$ that is NLT 85.0% and NMT 110.0% of labeled amount of Simethicone.

APPEARANCE : Milky white viscous liquid.

SPECTROSCOPIC IDENTIFICATION TESTS : Infrared Spectroscopy. Meets the requirement.

ASSAY : 30.0% w/w of Polydimethylsiloxane.
(Lt.85.0% - 110.0% of the labeled amount of Simethicone).

MICROBIAL ENUMERATION TESTS
TOTAL AEROBIC MICROBIAL COUNT : NMT 10^2 cfu/g.

DEFOAMING ACTIVITY : Not more than 15seconds.

	Prepared by	Checked by	Reviewed by	Approved by
Name	Vaishali Badekar	Leena Panchal	Meena Vaidya	Kalpakam Venkatesan
Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 20/06/2022	 20/06/2022	 21/06/2022	 21/06/2022



RioCare India Private Limited

Plot No. R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, District: Thane,
Maharashtra, INDIA

FINISHED PRODUCT SPECIFICATION

Simethicone Emulsion (Simul-73)	Effective Date : 22/06/2022	Reference
Specification No.: SPEC-SML-01-08	Supersedes doc. : 01/04/2022	INH

EXPIRY DATE : 30 months from the date of manufacture.

STORAGE CONDITION : Store in air tight containers.
Recommended temperature 25 - 40°C

Reason for review:

CCD No.: CC/20-22/054 dt. 23/03/2022 : Updated as per USP 44.
CCD No.: CC/22-24/001 dt. 16/06/2022 : As per official USP notification the current version is changed from USP 44 to USP-NF 2022, Issue 1.

	Prepared by	Checked by	Reviewed by	Approved by
Name	Vaishali Badekar	Leena Panchal	Meena Vaidya	Kalpakam Venkatesan
Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 20/06/2022	 20/06/2022	 21/06/2022	 21/06/2022