

Sodium Stearyl Fumarate NF/EP/JP

Lubripharm® SSF

Retest Date: 5.0 year(s) from the date of Mfg.

Product Code : 550-1100

CHARACTERISTICS

Identification (USP) for Sodium Stearyl Fumarate	Conforms
Identification (EP) for Sodium Stearyl Fumarate	Conforms
Identification (JP) for Sodium Stearyl Fumarate	Conforms
Identification by IR (USP)	Matches USP reference standard

PHYSICAL

Description (USP) for Sodium Stearyl Fumarate	White to almost white powder
Water (By Karl Fischer, USP) for Sodium Stearyl Fumarate	NMT 5.0 %
Saponification value (USP) for Sodium Stearyl Fumarate (db)	142.2 - 146.0 mg/KOH
Impurity Sodium Stearyl maleate (TLC, USP) for Sodium Stearyl Fumarate	NMT 0.25 %
Impurity Stearyl Alcohol (TLC, USP) for Sodium Stearyl Fumarate	NMT 0.5 %
Description (EP) for Sodium Stearyl Fumarate	White to almost white powder
Water (By Karl Fischer, EP) for Sodium Stearyl Fumarate	NMT 5.00 %
Solubility (EP) for Sodium Stearyl Fumarate	Conforms
Description (JP) for Sodium Stearyl Fumarate	White to almost white powder
Water (By Karl Fischer, JP) for Sodium Stearyl Fumarate	NMT 5.00 %
Saponification value (JP) for Sodium Stearyl Fumarate	142.0 - 146.0 mg/KOH

CHEMICAL

(1) Lead (USP) for Sodium Stearyl Fumarate	NMT 0.001 %
Assay (on dry basis, USP) for Sodium Stearyl Fumarate	99.0 - 101.5 %
Residual solvent (USP) Acetone for Sodium Stearyl Fumarate	NMT 300 ppm

Company Name:

Signer's Name:

Signature:

Date:

(Company stamp if available)

Signed electronically by
 SPI Pharma Quality Assurance

(1) These tests are on reduced testing status.
 (db) Results are reported on a dried basis

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Residual solvent (USP) Ethyl Acetate for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (USP) Toluene for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (USP) Methanol for Sodium Stearyl Fumarate	NMT 300 ppm
Assay (on dry basis, EP) for Sodium Stearyl Fumarate	99.0 - 101.5 %
Residual solvent (EP) Acetone for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (EP) Ethyl Acetate for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (EP) Toluene for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (EP) Methanol for Sodium Stearyl Fumarate	NMT 300 ppm
Related substance any impurity (EP) for Sodium Stearyl Fumarate	NMT 0.50 %
Related substance total impurities (EP) for Sodium Stearyl Fumarate	NMT 5.00 %
Assay (on dry basis, JP) for Sodium Stearyl Fumarate	99.0 - 101.5 %
Residual solvent (JP) Acetone for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (JP) Ethyl Acetate for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (JP) Toluene for Sodium Stearyl Fumarate	NMT 300 ppm
Residual solvent (JP) Methanol for Sodium Stearyl Fumarate	NMT 300 ppm
Related substance any impurity (JP) for Sodium Stearyl Fumarate	NMT 0.50 %
Related substance (JP) total impurities for Sodium Stearyl Fumarate	NMT 5.00 %
(1) Arsenic (JP) for Sodium Stearyl Fumarate	NMT 2 ppm

Company Name:

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SPI Pharma Inc
1711 Tiles Court
Grand Haven, MI 49417
USA
PH: 616-935-6900



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MICROBIAL

Microbial Total Aerobic Count	NMT 100 cfu/g
Total Fungi & Yeast Count	NMT 100 cfu/g
E. coli	Absence
P. aeruginosa	Absence
Salmonella species	Absence
S. aureus	Absence

Company Name:

Signer's Name:

Signature:

Date:

(Company stamp if available)

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SPI Pharma Quality Assurance

(db) Results are reported on a dried basis

550-1100-05 Effective (dd.mm.yyyy) 26.07.2019

This material is produced for SPI by :
Standard Chem. & Pharm. Co. ,LTD.
No. 154 Kaiyuan Road
Sinying District, Tainan City 73055,
Taiwan, R.O.C 886-6-6332445

Effective Date 26 Jul 2019

Signature Manifest**Document Number:** SPI-SPEC-251**Revision:** 05**Title:** 550-1100-Lubripharm ® SSF NF/EP/JP Sodium Stearyl Fumarate

All dates and times are in Eastern Time.

GH-19-126**QC Approval**

Name/Signature	Title	Date	Meaning/Reason
Rachelle Long (RLONG1)	QC Team Leader	23 Jul 2019, 07:05:30 PM	Approved
Michael Todd (MTODD)	R&D Senior Scientist	24 Jul 2019, 01:47:10 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Christopher Golden (CGOLDEN)	Site Head of Quality	24 Jul 2019, 04:35:24 PM	Approved

Effective Date 26 Jul 2019