

Name - Sodium Stearyl Fumarate Ph. Eur / USP - NF / JPE / ChP / FCC
Batch No - PVO/XXX/YYYY **Specification No.** -FPS-SSF-17-03
Manufacturing Date - Month YYYY **Expiry Date** - Month YYYY
Release Date - DD/MM/YY **Manufacturing Site** - Gummidipoondi, India

Description		
Appearance	White or almost white, fine powder with agglomerates of flat, circular particles	
Solubility	Practically insoluble in water, slightly soluble in methanol, practically insoluble in acetone and in ethanol	
Test	Specifications	Reference
Identification by IR (1)	The Infrared absorption spectrum of the sample should be concordant with that of Sodium Stearyl Fumarate Working Standard spectrum.	Ph. Eur / NF / JPE / ChP
Identification by Sodium Salt (2)	The formation of the precipitate is accelerated by rubbing the inside wall of the test tube with a glass rod	JPE
Water	Maximum 5.0% w/w	Ph. Eur / NF / JPE / ChP
Lead	Not more than 2 PPM	USP / ChP
Heavy Metals	Not more than 20 PPM	USP / JPE / ChP
Arsenic	Not more than 1.5 PPM	JPE / ChP
Related substances by TLC I) Sodium stearyl maleate II) Stearyl alcohol	I) Not more than 0.25% II) Not more than 0.5%	NF / ChP
Related Substance by TLC	The spots are no darker than the spots obtained from the standard solution	JPE
Related substance by GC I) Any impurity II) Total impurity	I) Maximum 0.5% II) Maximum 5.0%	Ph. Eur / ChP
Fats and fixed oils Saponification value on anhydrous basis	142.2 - 146	NF / JPE / ChP
Residual Solvents	I) Acetone not more than 500 PPM II) Toluene not more than 890 PPM	By Gas Chromatography (GC)
Assay - On anhydrous basis	Not less than 99.0% - 101.5%	Ph. Eur / NF / JPE / ChP
Total Bacteria Count	Not more than 10 ³ cfu/gm	Ph. Eur / NF / JPE
Total Fungal Count	Not more than 10 ² cfu/gm	Ph. Eur / NF / JPE

Escherichia coli	Absent in 1 gm	Ph. Eur / NF / JPE
Pseudomonas Aeruginosa	Absent in 1 gm	Ph. Eur / NF / JPE
Staphylococcus aureus	Absent in 1 gm	Ph. Eur / NF / JPE
Salmonella	Absent in 10 gm	Ph. Eur / NF / JPE
Particle size distribution	d10: max. 2.5 µm d50: max. 20 µm d90: max. 45 µm	In house method
Specific surface area	1.2 - 2.0 m ² /g	In house method

Storage Conditions - Store in a closed condition at ambient temperatures and away from extreme weather conditions

Contact -
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