# Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

## Sodium Stearyl Fumarate

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

**Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**

### Document History and Schedule for the Adoption Process

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| Further follow-up action as required. | |

# Sodium Stearyl Fumarate

$C_{22}H_{39}NaO_4$ Mol. Wt. 390.5

Sodium Stearyl Fumarate contains not less than 99.0 per cent and not more than 101.5 per cent of $C_{22}H_{39}NaO_4$, calculated on the anhydrous basis.

**Category**. Pharmaceutical aid.

**Description.** A white powder.

## Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *sodium stearyl fumarate IPRS* or with the reference spectrum of sodium stearyl fumarate.

## Tests

**Limit of sodium stearyl maleate and stearyl alcohol**. Determine by thin-layer chromatography (2.4.17), coating the plate with silica gel G.

*Solvent mixture.* 2 volumes of *glacial acetic acid* and 8 volumes of *chloroform.*

*Test solution*. Dissolve 200 mg of substance under examination in the solvent mixture with the aid of ultrasound for 10 minutes and dilute to 10.0 ml with the solvent mixture.

*Reference solution (a)*. A 0.1 per cent w/v solution of *monostearyl maleate IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml with *chloroform*.

*Reference solution (b)*. A 0.1 per cent w/v solution of *stearyl alcohol IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml with *chloroform*.

*Mobile phase*. A mixture of 5 volumes of *hexane*, 5 volumes of *toluene* and 1 volume of *glacial acetic acid*.

Apply to the plate 5 µl of reference solution (a) and 10 µl of reference solution (b) and the test solution. Immerse the plate in a tank containing a layer of 10 mm of chloroform on the bottom. Allow the solvent to reach the upper edge of the spots. Dry the plate in cold air and repeat the procedure till spots having a linear shape. Allow the developing solvent system to rise about 15 cm. Dry the plate for 10 minutes and heat in oven at 90º for 2 minutes and allow to cool. Replace the plate in the chamber for another 15 cm development, remove the plate and allow to dry at room temperature for 15 minutes. Spray with a mixture of 1 volume of *sulphuric acid* and 9 volumes of *ethanol*. Dry the plate in an oven at 150º for 10 minutes and allow to cool. Dark spots appear on a light background. In the chromatogram obtained with the test solution, any spot corresponding to sodium stearyl maleate and stearyl alcohol is not more intense than the spot in the chromatogram obtained with reference solution (a) (0.25 per cent) and reference solution (b) (0.5 per cent), respectively. Faint spots at an Rf value of 0.9 may result from traces of distearyl maleate and distearyl fumarate.

**Lead** (2.3.15). Not more than 10 ppm.

**Saponification value** (2.3.37). 142.2 to 146.0, calculated on anhydrous basis.
Weigh 0.45 g, add 50 ml of *0.5 M ethanolic potassium hydroxide* and heat under a reflux condenser for 2 hours. Titrate the hot solution immediately with *0.1 M hydrochloric acid* using 1 ml of *phenolphthalein solution* as indicator, until the pink colour is discharged ($n_1$ ml). Repeat the operation without the substance under examination ($n_2$ ml). Calculate the saponification value from the expression $28.05(n_2\text{-}n_1)/w$, where w is the weight, in g, of the substance taken.

**Heavy metal** (2.3.13). 1.0 g complies with limit test for heavy metals, Method B (20 ppm).

**Water** (2.3.43). Not more than 5.0 per cent, determined on 0.5 g.

**Assay**. Weigh 0.25 g, dissolve in 10 ml of *chloroform* and 20 ml of *glacial acetic acid*. Titrate with *0.1 M perchloric acid*, using *quinaldine red solution* as indicator. Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.03905 g of $C_{22}H_{23}NO_7$.

**Storage**. Store protected from moisture, at a temperature not exceeding 30˚.

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**Solubility**. Page 293

Insert before, **Sodium Thiosulphate**

**Sodium Stearyl Fumarate**. Slightly soluble in *methanol*; practically insoluble in *water*.