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SPECIFICATION

LubriSanaq®

Sodium Stearyl Fumarate (Ph. Eur - USP/NF)

TEST PERFORMED	SPECIFICATIONS	METHOD
Description	White or almost white fine powder	Ph. Eur / USP-NF
Identification	IR spectrum matches with reference standard	Ph. Eur / USP-NF
Solubility	Practically insoluble in water, slightly soluble in methanol, practically insoluble in acetone and in ethanol.	Ph. Eur
Water (By Karl Fischer)	N.M.T. 5.0 %	Ph. Eur / USP-NF
Saponification value	142.20 – 146.00, calculated on the dried basis	USP-NF
Impurity (TLC)		
- Limit of sodium stearyl maleate	N.M.T. 0.25 %	USP-NF
- LImit of stearyl alcohol	N.M.T. 0.5 %	USP-NF
Lead	N.M.T. 0.001 %	USP-NF
Heavy Metals	N.M.T. 0.002 %	USP-NF
Assay	99.00 % - 101.50 % calculated on the anhydrous basis	Ph. Eur / USP-NF
Related substances any impurity	N.M.T. 0.50 %	Ph. Eur
Total Impurities	N.M.T. 5.00 %	Ph. Eur
Additional Specification		
Residual solvents		
- Acetone	N.M.T. 300ppm	USP-NF
- Ethyl Acetate	N.M.T. 300ppm	USP-NF
- Toluene	N.M.T. 300ppm	USP-NF
- Methanol	N.M.T. 300ppm	USP-NF