

PRODUCT
SPECIFICATION
BULLETIN

Alubra™ PG 100
Sodium Stearyl Fumarate USP, JPE, EP

FMC Tests

Test	Specification	Method
Description	Fine, white to off white powder	USP/NF, Ph. Eur., JPE
Solubility	Slightly soluble in methanol Practically insoluble in water	Ph. Eur.
Identification	By FTIR – comparison: sodium stearyl fumarate standard.	USP/NF, Ph. Eur., JPE
Water	Maximum 5.0 % (determined on 0.250 g.)	USP/NF, Ph. Eur., JPE
Lead	Not more than 0.001 %	USP/NF
Heavy metals	Not more than 0.002 %	USP/NF, JPE
Saponification value	Between 142.2 – 146.0	USP/NF, JPE
Limit of sodium stearyl malate	Not more than 0.25 %	USP/NF
Limit of stearyl alcohol	Not more than 0.50 %	USP/NF
Organic volatile impurities	Meets the requirement	USP/NF
Assay C ₂₂ H ₃₉ NaO ₄ (On anhydrous basis)	Between 99.0 % to 101.5 %	USP/NF, Ph. Eur., JPE
Related substance (Ph. Eur.)	Largest single impurity : Not more than 0.5 % Total impurities : Not more than 5.0 %	Ph. Eur.
Related substance (JPE)	Confirms	JPE
Identification II	Responds to qualitative test (1) for sodium salt	JPE
Arsenic (JPE)	Not more than 0.0002 %	JPE
Residual Solvent:	Complies with residual solvent Requirements in USP <467> and Ph. Eur. 5.4 for class 1,2,3 solvents See solvent statement.	USP/Ph. Eur.
Toluene	Not more than 890 ppm	GC (FMC Method)
Methanol	Not more than 3000 ppm	GC (FMC Method)



Alubra™

The lubricant that solves the insoluble.

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FMC Corporation

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Product Suitability

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