

CERTIFICATE OF ANALYSIS



Cat. No A-6105

Product 5-Aminolevulinic acid hydrochloride, GMP

delta-Aminolevulinic acid hydrochloride; 5-Amino-4-oxopentanoic acid HCl

CAS RN [5451-09-2]

M. F. C5H10ClNO3

Lot No. 0000000417

M. W. 167.59 g/mol

Test	Result	Specification
Appearance	white crystals	white to off-white crystals
Solution (5 % in water)	practically colorless, clear	practically colorless, clear
Water Content (K Fischer)	0.08 %	max. 0.5 %
Loss on Drying (105 °C, 3 hours, vacuum)	0.1 %	max. 0.5 %
Assay (HPLC)	99.8 %	98.0 - 102.0 %
Assay (argentometric titration)	99.0 %	98.5 - 101.5 %
Purity (HPLC; 5-Aminolevulinic acid methyl ester)	< 0.01 %	max. 0.15 %
Purity (HPLC; 5-Aminolevulinic acid isopropyl ester)	< 0.01 %	max. 0.15 %
Purity (HPLC; Phthalic acid)	< 0.01 %	max. 0.10 %
Purity (HPLC; 2,5-Bis- (beta-carboxyethyl)-pyrazine)	< 0.01 %	max. 0.15 %
Purity (HPLC; 5-N- (Phthaloyl)aminolevulinic acid methyl ester)	< 0.01 %	max. 0.10 %
Purity (HPLC; 5-N- (Phthaloyl)aminolevulinic acid)	< 0.01 %	max. 0.10 %
Purity (HPLC; individual unknown impurities)	< 0.01 area-%	max. 0.1 area-%
Purity (HPLC; sum of all unknown impurities)	< 0.01 area-%	max. 0.5 area-%
Melting Point	153 °C	151 - 155 °C
Residual Solvents (GC; sum of 2-propanol + acetone)	< 0.49 %	max. 0.49 %
Sulfated Ash	0.02 %	max. 0.1 %
Ammonium Content	< 0.1 %	max. 0.3 %
HPLC	corresponds	retention times of standard and sample are identical
FTIR	corresponds	corresponds to reference spectrum
Recommended Retest Date	12/2011	

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