



Specification for L-Arginine, Free Base, cGMP, USP, EP, JP, bioCERTIFIED(TM) (A9601)

Item Number	A9601
Item	L-Arginine, Free Base, cGMP, USP, EP, JP, bioCERTIFIED(TM)
CAS Number	74-79-3
Molecular Formula	C ₆ H ₁₄ N ₄ O ₂
Molecular Weight	174.20
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS, USP)	98.5	101.5 %
Assay (Dried Basis, JP, EP)	99.0	101.0 %
Specific Rotation (20°C, EP)	+25.5° to +28.5°	
Specific Rotation (20°C, JP)	+26.9° to +27.9°	
Specific Rotation (25°C, USP)	+26.3° to +27.7°	
pH (JP)	10.5	12.0
LOSS ON DRYING (USP, EP)		0.5 %
LOSS ON DRYING (JP)		0.3 %
Appearance of Solution (EP, JP)		TO PASS TEST
RESIDUE ON IGNITION (USP)		0.3 %
Residue on Ignition/Sulfated Ash (JP, EP)		0.1 %
CHLORIDE (USP)		0.05 %
CHLORIDE (JP)		0.21 %
Sulfate (USP, EP)		0.03 %
SULFATE (JP)		0.028 %
Organic Impurities (USP):		
INDIVIDUAL IMPURITIES		0.5 %
TOTAL IMPURITIES		2.0 %
Ninhydrin-Positive Substances (EP):		
Any Ninhydrin-Positive substance		0.2 %
TOTAL		0.5 %
RELATED SUBSTANCES (JP), RELATED COMPOUNDS (USP) CONFORMS		TO PASS TEST
ARSENIC		1.5 ppm

Test	Specification	
	Min	Max
Heavy Metals (as Pb, JP)		10 ppm
AMMONIUM (EP)		TO PASS TEST
AMMONIUM (JP)		0.2 %
Iron (USP)		30 ppm
Iron (EP, JP)		10 ppm
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		
TOTAL AEROBIC BACTERIA COUNT (TABC)		1000 CFU/g
YEAST AND MOLD		100 CFU/g
COLIFORMS		Negative/g
ESCHERICHIA COLI		Negative/10 g
SALMONELLA		Negative/25 g
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

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