



**Specification for Edetate Disodium, USP, EP, JP,
bioCERTIFIED (TM) (E9600)**

Item Number	E9600
Item	Edetate Disodium, USP, EP, JP, bioCERTIFIED (TM)
CAS Number	6381-92-6
Molecular Formula	$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$
Molecular Weight	372.24
MDL Number	
Synonyms	Ethylenediaminetetraacetic Acid Disodium Salt ; EDTA, Disodium ; (Ethylenedinitrilo)tetraacetic Acid Disodium

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS, USP)	99.0	101.0 %
ASSAY (AS DIHYDRATE, EP)	98.5	101.0 %
ASSAY (AS DIHYDRATE, JP)	99.0 %	
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS	
CLARITY AND COLOR OF SOLUTION (JP)	CLEAR AND COLORLESS	
pH OF A 5% SOLUTION @ 25°C (USP)	4.0	6.0
pH OF A 5% SOLUTION @ 20°C (EP)	4.0	5.5
pH OF A 1% SOLUTION @ 25°C (JP)	4.3	4.7
LOSS ON DRYING (USP)	8.7	11.4 %
RESIDUE ON IGNITION (JP)	37.0	39.0 %
CALCIUM (USP)	NO PRECIPITATE FORMS	
CYANIDE (JP)	NO MORE COLOR THAN CONTROL	
IRON (EP)		80 ppm
HEAVY METALS (JP)		10 ppm
ARSENIC (JP)		2 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
NITRILOTRIACETIC ACID (USP)		0.1 %
IMPURITY A (EP)		0.1 %
MICROBIAL LIMITS:		
BACTERIAL ENDOTOXIN (BET)		2.5 EU/mg
TAMC		1000 CFU/g

Test	Specification	
	Min	Max
TYMC		100 CFU/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RED COLOR IS DISCHARGED	
IDENTIFICATION (C)	POSITIVE FOR SODIUM	
IDENTIFICATION (B) EP	NO PRECIPITATE IS FORMED	
IDENTIFICATION (C) EP	NO PRECIPITATE IS FORMED	
IDENTIFICATION (1) JP	PURPLE COLOR DEVELOPS	
IDENTIFICATION (2) JP	240	244°C
IDENTIFICATION (3) JP	POSITIVE FOR SODIUM	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
MONOGRAPH EDITION.		
MONOGRAPH EDITION..		
RESIDUAL SOLVENTS	AS REPORTED	

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