

Item Number	SP320
Item	Spironolactone, USP
CAS Number	52-01-7
Molecular Formula	C ₂₄ H ₃₂ O ₄ S
Molecular Weight	416.57
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
ASSAY (DRIED BASIS)	97.0	103.0 %
SPECIFIC ROTATION	-41° to -45°	
LOSS ON DRYING		0.5 %
MERCAPTO-COMPOUNDS		0.10 ml
ORGANIC IMPURITIES:		
SPIRONOLACTONE RELETED COMPOUND B		0.2 %
SPIRONOLACTONE RELETED COMPOUND A		0.2 %
SPIRONOLACTONE RELETED COMPOUND C		0.2 %
SPIRONOLACTONE RELETED COMPOUND D		0.3 %
SPIRONOLACTONE EPIMER		0.3 %
SPIRONOLACTONE RELATED COMPOUND I		0.1 %
ANY UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
RESIDUAL SOLVENTS:	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	
CLASS 2 (solvent) / N,N-DIMETHYLFORMAMIDE	.	
CLASS 2 (solvent) / TETRAHYDROFURAN	.	
CLASS 3 (solvent) / ACETONE	.	
CLASS 3 (solvent) / DIMETHYL SULFOXIDE	.	

Test	Specification	
	Min	Max
CLASS 3 (solvent) / ETHANOL	.	
CLASS 3 (solvent) / TRIETHYLAMINE	.	
OTHER RESIDUAL SOLVENTS: DIETHYL MALONATE	.	
OTHER RESIDUAL SOLVENTS: TRIETHYL ORTHOFORMATE		5000 ppm
MONOGRAPH EDITION		
EXPIRATION DATE		
DATE OF MANUFACTURE		

Spectrum Chemical Mfg Corp

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