



**Specification for Ketorolac Tromethamine, USP,
bioCERTIFIED (TM) (KE902)**

Item Number	KE902
Item	Ketorolac Tromethamine, USP, bioCERTIFIED (TM)
CAS Number	74103-07-4
Molecular Formula	$C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$
Molecular Weight	376.40
MDL Number	
Synonyms	Toradol® ; (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic Acid Compound with 2-Amino-2-(hydroxymethyl)-1,3-propanediol (1 : 1) ; Ketorolac Trometamol

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	98.5	101.5 %
IDENTIFICATION (IR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (HPLC)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (TLC)	YELLOW SPOTS WITH PINK TO PURPLE BORDERS DEVELOP	
pH OF A 1 IN 100 SOLUTION	5.7	6.7
LOSS ON DRYING		0.5 %
ORGANIC IMPURITIES:		
IMPURITY HAVING A 0.54 RELATIVE RETENTION TIME		0.5 %
KETOROLAC 1-HYDROXY ANALOG		0.1 %
IMPURITY HAVING A 0.66 RELATIVE RETENTION TIME		0.5 %
KETOROLAC 1-KETO ANALOG		0.1 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.5 %
TOTAL IMPURITIES		1.0 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		

Test	Specification	
	Min	Max
BACTERIAL ENDOTOXINS		5.8 USP EU/mg
TOTAL AEROBIC MICROBIAL COUNT		10 ³ cfu/g
TOTAL YEASTS AND MOLDS COUNT		10 ² cfu/g
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

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