

Item Number	O1405
Item	Omeprazole, USP
CAS Number	73590-58-6
Molecular Formula	C <sub>17</sub> H <sub>19</sub> N <sub>3</sub> O <sub>3</sub> S
Molecular Weight	345.42
MDL Number	
Synonyms	5-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]benzimidazole

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
COMPLETENESS OF SOLUTION	NOT LESS CLEAR THAN STANDARD	
LIMIT OF OMEPRAZOLE RELATED COMPOUNDS F AND G		350 ppm
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:		
5-METHOXY-1H-BENZIMIDAZOL-2-THIOL		0.15 %
OMEPRAZOLE RELATED COMPOUND E		0.15 %
OMEPRAZOLE RELATED COMPOUND I		0.15 %
DESMETHOXY OMEPRAZOLE		0.15 %
OMEPRAZOLE RELATED COMPOUND A		0.15 %
OMEPRAZOLE 4-CHLORO ANALOG		0.15 %
UFIPRAZOLE		0.15 %
ANY OTHER INDIVIDUAL IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
IDENTIFICATION (A)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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