

Specification

Technical Data Sheet

Product Name	Omeprazole
Product No	86694532
CAS Number	73590-58-6
Storage Temperature	2 to 8 °C
Molecular Weight	345.42
	Specification
Appearance	A white or almost white powder
Heavy metals	≤0.002%
Loss on Drying	≤0.5%
5-Methoxy-1H-benzimidazol-2-thiol	≤0.15%
Absorbance	Not greater than 0.10 at 440nm (≤350ppm)
Desmethoxy omeprazole	≤0.15%

Specification

Omeprazole 4-chloroanalog	≤0.15%
Omeprazole N-oxide	≤0.15%
Omeprazole sulfone	≤0.15%
Omeprazole sulfone N-oxide	≤0.15%
Residual solvent - Benzene	≤1ppm
Residual Solvent - Methanol	≤1000ppm
Residual solvent - methylene chloride	≤ 100ppm
Residual solvent - Toluene	≤ 300ppm
Residue on Ignition	≤0.1%
Specification	USP 39
Total Impurities	≤1.0%
Ufiprazole	≤0.15%
Any other individual impurity	≤0.10%
Assay (HPLC)	98.0% - 102.0%
Residual solvent - acetone	≤1500ppm
