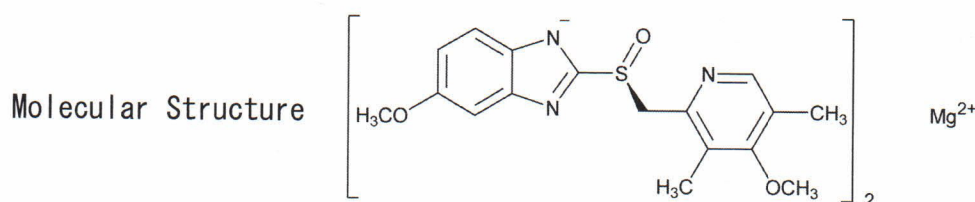


Batch no 22101501  
Mf date Oct 15 2022  
Retest Oct 14 2025



Molecular Formula  $C_{34}H_{36}MgN_6O_6S_2 \cdot 3H_2O$   
Molecular Weight 767.17  
CAS Registry Number 217087-09-7

Aug 06 2024

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White to slightly colored powder	Conforms
Solubility	Dissolved in methanol, slightly soluble in water, almost insoluble in heptane	Conforms
Identification	IR	Positive
Appearance of solution	At 440 nm, Absorbance $\leq 0.2$	0.08
Water	6.0 ~ 8.0%	6.45%
Related substances	Omeprazole N-oxide $\leq 0.1\%$	0.03%
	Omeprazole sulfonamide compounds $\leq 0.2\%$	0.1%
	Other unknown monohetero $\leq 0.1\%$	0.06%
	Total impurities $\leq 0.5\%$	0.24%
Enantiomeric purity	Enantiomeric $\leq 0.2\%$	0.09%
Magnesium content	3.3 ~ 3.55%	3.48%
Residual solvents	Methanol $\leq 3000$ ppm	166 ppm
	Isopropyl alcohol $\leq 5000$ ppm	ND
	Acetone $\leq 5000$ ppm	325 ppm
	Ethyl acetate $\leq 5000$ ppm	ND
	Toluene $\leq 890$ ppm	55 ppm
Assay (oab)	98.0 ~ 102.0%	99.23%

Packaging & storage	Preserve in tight containers, protected from light. Store at room temperature
Conclusion	Material complies with USP42