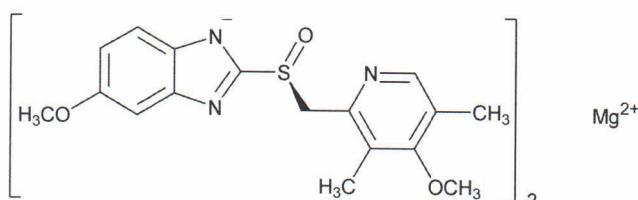




Batch no 22101501
Mf date Oct 15 2022
Retest Oct 14 2024

Molecular Structure



Molecular Formula $C_{34}H_{36}MgN_6O_6S_2 \cdot 3H_2O$

Molecular Weight 767.17

CAS Registry Number 217087-09-7

May 17 2023

Tests	Specifications	Results
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 ≤ 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 ≤ 3000 ppm	166 ppm
	Isopropyl alcohol ≤ 5000 ppm	ND
	Acetone ≤ 5000 ppm	325 ppm
	Ethyl acetate ≤ 5000 ppm	ND
	Toluene ≤ 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

