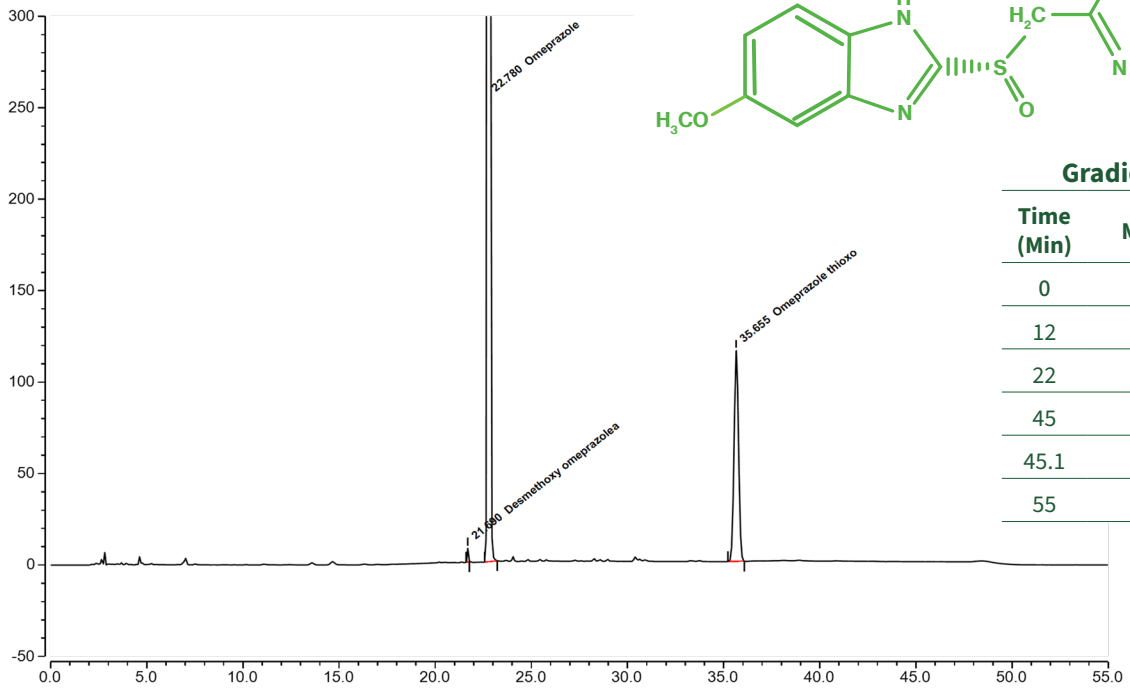
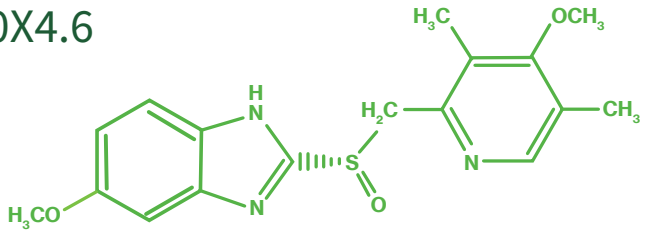
Omeprazole Related Substances (USP)

On Endurus® C8 Classic 5µm 250X4.6





Gradient Table

Time (Min)	MPA	MPB
0	75	25
12	75	25
22	50	50
45	50	50
45.1	75	25
55	75	25

Test Condition (As USP)
Column:
Endurus® C8 Classic 250x4.6 mm, 5µm
Injection: 40 µL
Detection: UV 264 nm
Flow Rate: 0.8 mL/min
Mobile Phase:
B: Acetonitrile
A: Dissolve 0.725 g of monobasic sodium phosphate and 4.472 g of anhydrous dibasic sodium phosphate in 1000 mL of water. Dilute 250 mL of this solution with water to 1000 mL. If necessary, adjust with phosphoric acid to a pH of 7.0.
Diluent: Acetonitrile and Buffer (1:3)
Temperature: Ambient
Autosampler temperature: 5°C
Gradient: See Table
Sample preparation:
0.6 mg/mL of Omeprazole in Diluent.

Chromatographic data

No.	Compound	Retention Time (min)	Tailing Factor	RRT
1	Desmethoxy omeprazolea	21.69	0.99	0.95
2	**Omeprazole**	**22.78**	**1.02**	**1**
3	Omeprazole thioxo	35.655	1.02	1.57

omeprazole exerts its therapeutic effects by selectively and irreversibly inhibiting the H+/K+-ATPase system in gastric parietal cells. This inhibition leads to a reduction in stomach acid secretion, alleviating symptoms associated with acid-related disorders. Understanding the biochemical mechanism of omeprazole's action provides insights into its clinical utility and underscores its role as a cornerstone therapy for acid-peptic diseases.

As per United States Pharmacopeia
Suitability requirements

Tailing factor: NMT 1.5
Relative retention time (RRT): 1.0 for omeprazole

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