

Waters

Stability-Indicating Assays using SunFire™ Columns

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SunFire™ C₁₈ analytical columns are designed to provide maximum loadability in simple mobile phase conditions, high peak capacities and excellent peak shapes.

Lansoprazole is used to treat ulcers, gastroesophageal reflux disease, and conditions where the stomach produces too much acid. Stability-indicating assays are analytical methods that accurately quantitate the active ingredients without interference from other components in the sample, such as degradation products. This active ingredient was degraded under acidic conditions to create potential interfering degradants. A 5-min scouting gradient from 5 to 95% B was first run to determine the isocratic mobile phase conditions listed below (Figure 1).

Experimental Conditions

HPLC Conditions

Column: SunFire™ C₁₈ 4.6 × 150 mm, 5.0 μm
Part Number: 186002559
Mobile Phase A: 20 mM HCOO⁻NH₄⁺, pH 3.0

Mobile Phase B: Acetonitrile

Flow Rate: 1.4 mL/min

Isocratic: 73%A: 27%B

Injection Volume: 5.0 μL

Sample Diluent: 8:17 H₂O:ACN

Sample Concentration: 4 mg/mL

Temperature: RT

Detection: UV @ 254 nm

Sampling rate: 5 pts/sec

Time Constant: 1

Instrument: Waters Alliance® 2695, with 2996 PDA

Software: Empower™

Degradation Conditions

Temperature: RT

10 mg of Lansoprazole + 0.4 mL of 1 N HCl

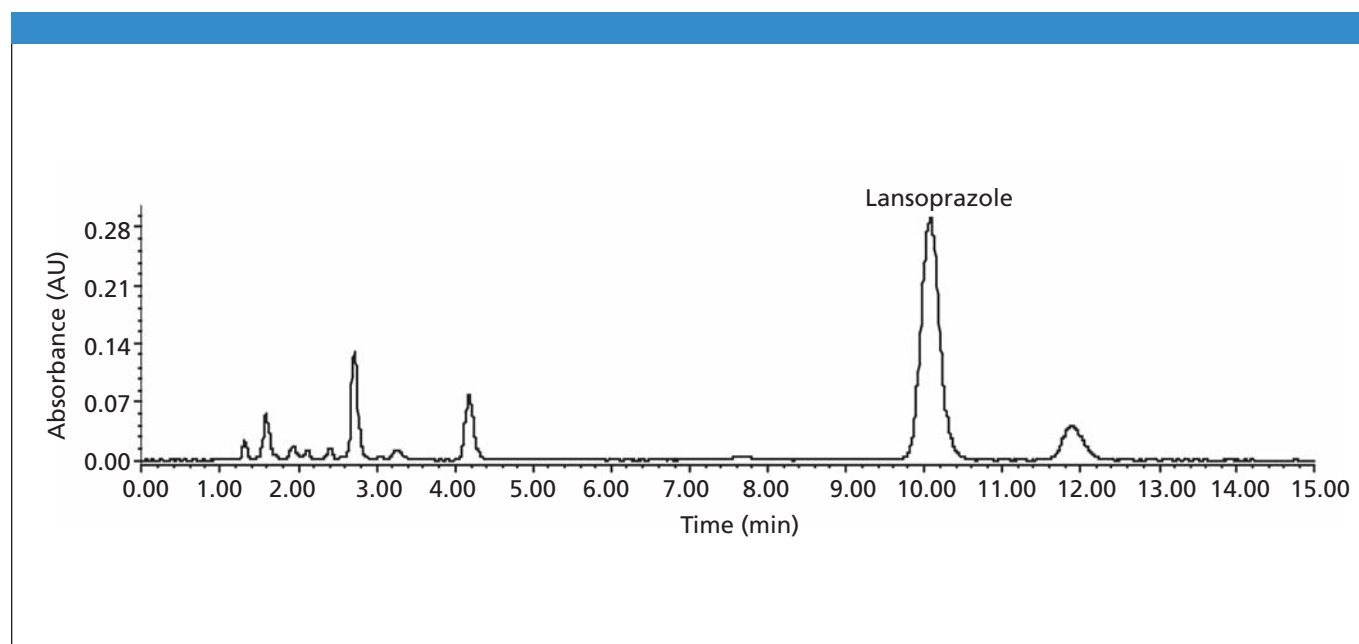


Figure 1: Full-scale chromatogram of degraded lansoprazole.

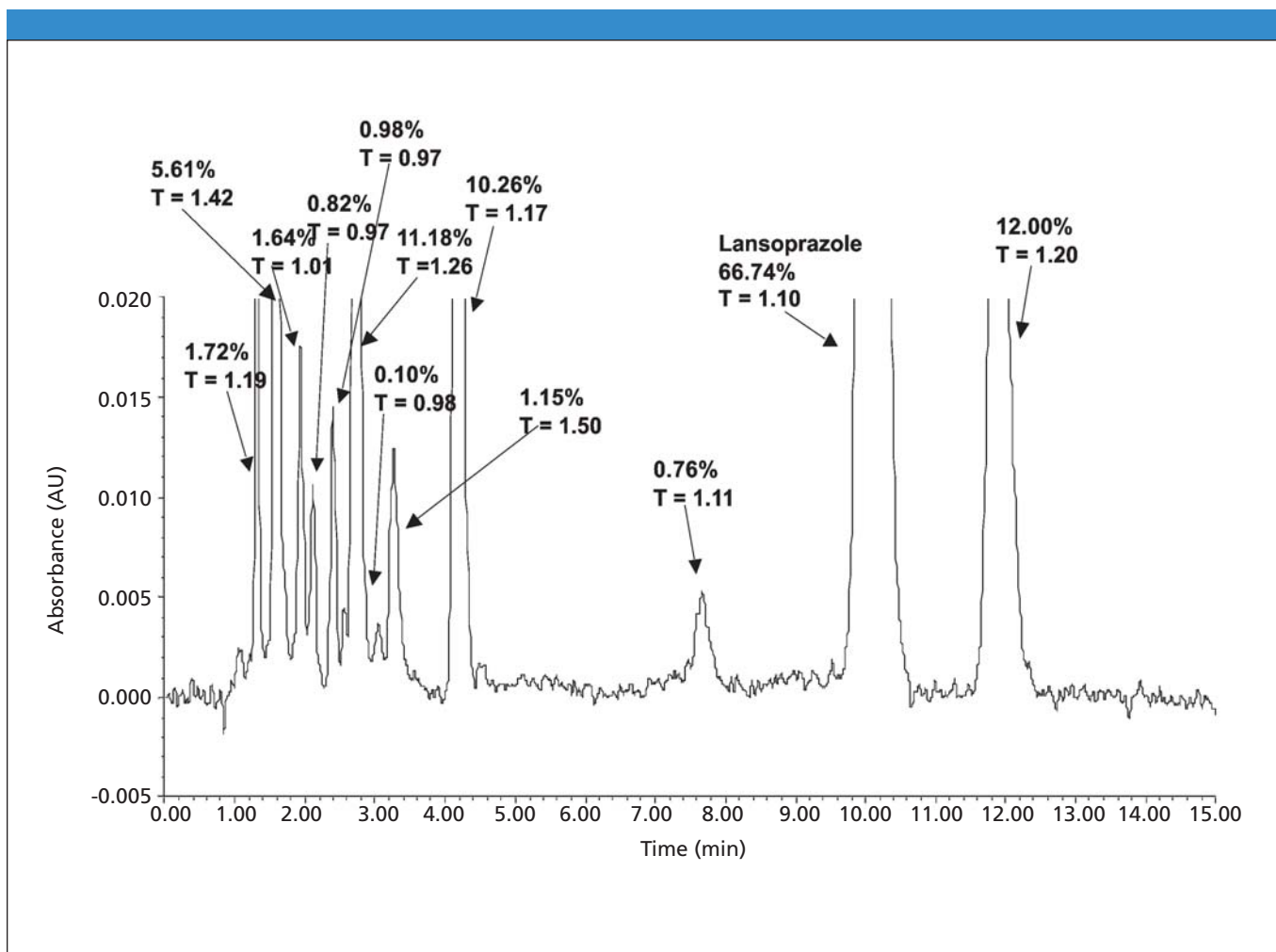


Figure 2: Enhanced baseline separation of degraded lansoprazole. Percentages are the percent of lansoprazole. T values are USP tailing factors.

Stirred for 20 s

Reaction quenched with 0.4 mL of 1 N NaOH, then diluted with 1.7 mL ACN

Lansoprazole degraded 34%

Results

As shown in Figure 1, the acidic degradation of lansoprazole results in the formation of several degradants that are cleanly separated from lansoprazole. Additionally, the excellent loading capacity of the SunFire™ C₁₈ analytical column allows a significant amount of material to be injected on the column, allowing for the detection of low levels of degradants and/or impurities, as shown in Figure 2.

Conclusions:

SunFire™ columns provide excellent peak shapes, efficiencies, and loading for stability indicating methods.

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