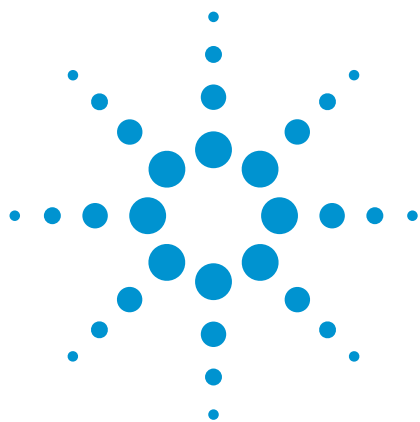




USP Analysis of Malic Acid on an Agilent Hi-Plex H Column

Application Note

Pharmaceutical

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Introduction

Maleic acid and fumaric acid are dicarboxylic acids consisting of an ethylene group connecting the two carboxylic acid groups. Maleic acid is the *cis* isomer of butenedioic acid, and fumaric acid is the *trans* isomer; therefore, both compounds are very similar in structure to each other and are closely related to malic acid.

The USP method for malic acid, requiring it to be separated from maleic acid and fumaric acid, specifies a 6.5×300 mm column that contains packing L17 (a strong cation exchange resin consisting of sulfonated crosslinked styrene/divinylbenzene copolymer in the hydrogen form). UV detection at 210 nm is required.



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Materials and Reagents

Column	Agilent Hi-Plex H, 6.5 × 300 mm, 8 µm (p/n PL1F70-6830)
Mobile phase	0.01 M H ₂ SO ₄
Flow rate	0.6 mL/min
Temperature	37 °C
Detector	UV at 210 nm

Standard Preparation

A solution containing 1 mg/mL of malic acid, 10 µg/mL of fumaric acid, and 4 µg/mL of maleic acid was made up in mobile phase. Twenty microliters of this solution was then injected on to the column.

Conclusion

Maleic acid and fumaric acid, despite being structural isomers of the same compound, elute at very different retention times. Therefore, they are very well separated by the Agilent Hi-Plex H column. Malic acid, however, elutes closer to maleic acid but can be separated to at least baseline resolution. These results show that the Hi-Plex H is a good choice of column for this particular application.

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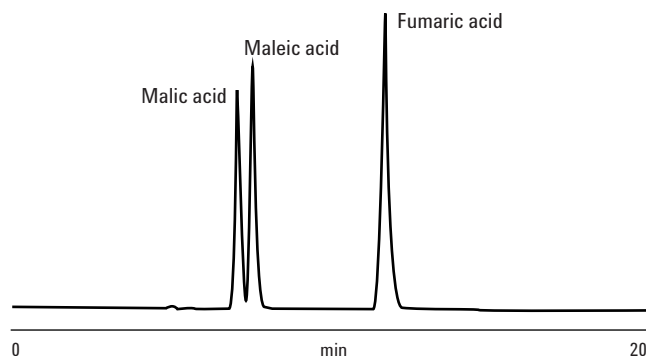


Figure 1. USP analysis of malic acid on an Agilent Hi-Plex H column.

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