

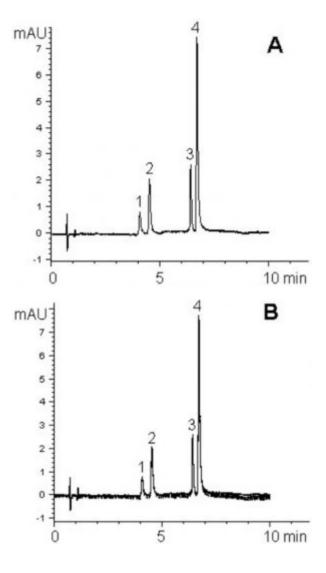
# Stability Testing of Tetracycline HCl Capsules - AppNote

## Robust, high-throughput Separation of API from its Degradation Products

Figure A shows the chromatogram obtained from a single injection of the degraded Tetracycline capsule extract. Tetracycline is well-resolved from its three main degradation products, the identities of which were confirmed by individual standards under non-degrading conditions.

Amine-containing analytes such as these often require the use of an ion-pairing agent in the Mobile Phase in order to reduce Peak tailing from Silanolic interactions. However, ion-pairing agents often lead to poor reproducibility and long equilibration times due to slow uptake and release of these agents from the Column. In this Method, ion-pairing agents are not necessary to obtain good Peak shapes.

Figure B shows an overlay of five sequential injections of the degraded Tetracycline solution, illustrating the Robustness of the Method. Retention time %RSDs for all of the analytes were < 0.1%. In addition, the post time was minimal (3 minutes).



Printed from the Chrom Resource Center
Copyright 2024, All Rights Apply
MicroSolv Technology Corporation

9158 Industrial Blvd. NE, Leland, NC 28451 tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com



#### Peaks:

- 1. 4-Epitetracycline
  - 2. Tetracycline
- 3. 4-Epianhydrotetracycline
  - 4. Anhydrotetracycline

### **Method Conditions**

Column: Cogent Bidentate C18<sup>™</sup>, 4μm, 100Å

**Catalog No.:** 40018-75P **Dimensions:** 4.6 x 75mm

**Mobile Phase:** 

A: DI Water / 0.1% Formic Acid B: Acetonitrile/ 0.1% Formic Acid

Gradient:

Time (minutes)	%B
0	10
4	30
6	80
7	10

**Post Time:** 3 minutes **Flow rate:** 1mL / minute

**Detection:** UV @ 360nm (0-5 minutes) 430nm (5-7 minutes)

#### **Sample Preparation:**

Stock Solution: 10mg capsule contents were diluted with 10mL 1.0 HCI and sonicated for 10 minutes. 1mL aliquot was diluted to 20mL with DI Water. Solution was heated at 80°C for 30 minutes.

Working Solution: Stock Solution was then diluted to 100mL with DI Water and filtered through a 0.45µm Nylon Syringe Filter (MicroSolv Technology). Stock solution was diluted 10x using Printed from the Chrom Resource Center Copyright 2024, All Rights Apply

**Notes:** Tetracycline is a broad-spectrum antibiotic widely used in both human and recording to the broading to degrade primarily by two pathways: Dehydration and Epimerization. 9158 Industrial Blvd. NE, Leland, NC 28451

tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com





Attachment

No 122 Stability Testing of Tetracycline HCl Capsules pdf 0.3 Mb Download File

Printed from the Chrom Resource Center
Copyright 2024, All Rights Apply
MicroSolv Technology Corporation

9158 Industrial Blvd. NE, Leland, NC 28451 tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com