

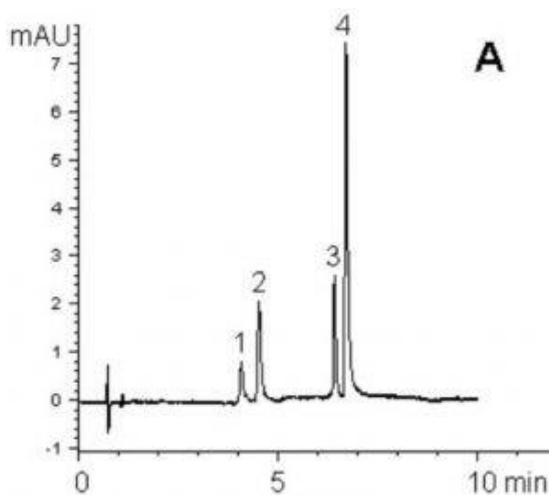
Tetracycline HCl Capsules Stability Testing - AppNote

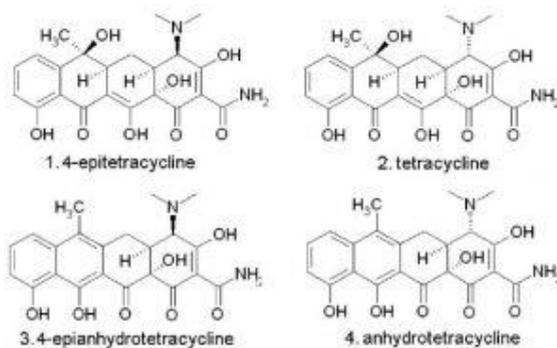
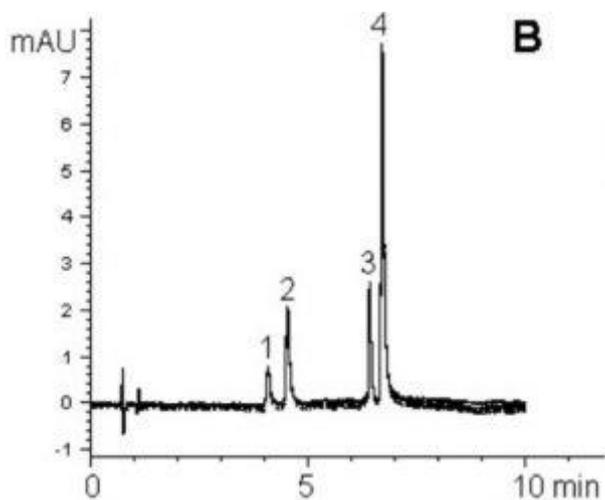
Robust, high-throughput Separation of API from its Degradation Products 4-Epitetracycline, Tetracycline, 4-Epianhydrotetracycline, Anhydrotetracycline

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).





Peaks: 1. 4-Epitetracycline, 2. Tetracycline, 3. 4-Epianhydrotetracycline, 4. Anhydrotetracycline

Method Conditions

Column: Cogent Bidentate C18™, 4 μm, 100 Å

Catalog No.: 40018-75P

Dimensions: 4.6 x 75 mm

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: 1 mL / minute

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

Sample Preparation:

- **Stock Solution:** 10 mg capsule contents were diluted with 10mL 1.0 HCl and sonicated for 10 minutes. 1 mL aliquot was diluted to 20 mL with DI Water. Solution was heated at 80°C for 30 minutes.
- **Working Solution:** Stock Solution was then diluted to 100 mL with DI Water and filtered through a 0.45 µm Nylon Syringe Filter (MICROSOLV Technology). Stock solution was diluted 10x using 0.01N HCl diluent before injection.

Notes: Tetracycline is a broad-spectrum antibiotic widely used in both human and veterinary medicine. It is known to degrade primarily by two pathways: Dehydration and Epimerization.



Attachment No 122 Stability Testing of Tetracycline HCl Capsules pdf 0.3 Mb [Download File](#)

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