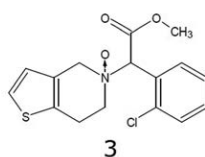
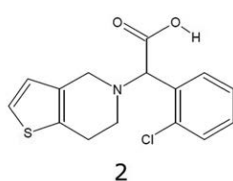
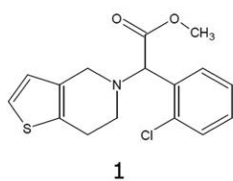
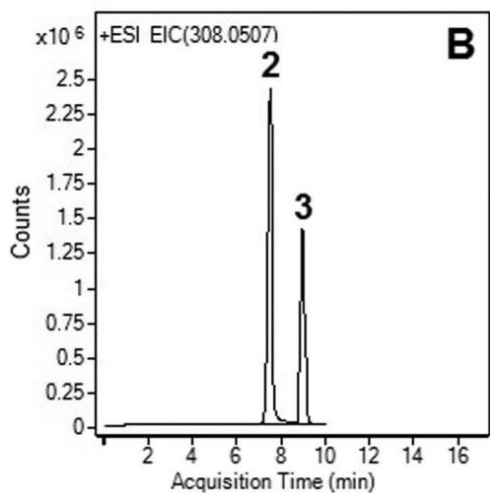
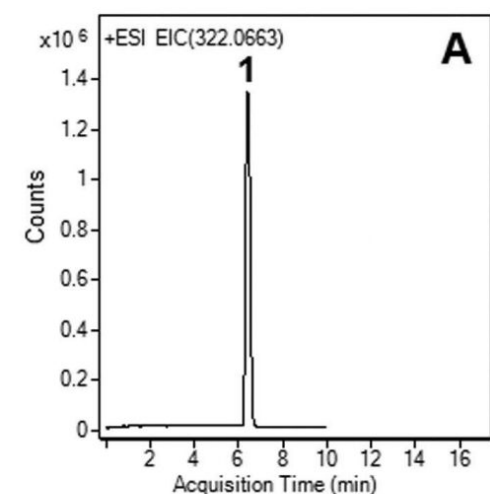


## Analysis of Clopidogrel with LCMS – AppNote

### Analysis of the API and Degradants

A Sensitive, Selective, and rapid LCMS Method was developed for the simultaneous Quantification of Clopidogrel (Plavix®) and degradants.

This Method can be used for the determination of Clopidogrel in commercial tablets for Quality Control with an application for content uniformity test. The Method is also stability-indicating as it is suitable for the determination of the API in the presence of its degradation products under all stress conditions using HCL, NaOH, light and Hydrogen Peroxide.



### Peaks:

1. API: Clopidogrel,  $m/z$  322.0663  $[M+H]^+$
2. Degradant: Clopidogrel Acid,  $m/z$  308.0507  $[M+H]^+$

3. Degradant: Clopidogrel N-oxide, m/z 338.02 [M+H]<sup>+</sup>

## Method Conditions

**Column:** Cogent Diamond Hydride™, 4μm, 100Å

**Catalog No.:** 70000-15P-2

**Dimensions:** 2.1 x 150mm

**Mobile Phase:**

A: DI Water / 0.1% Formic Acid (v/v)

B: Acetonitrile / 0.1% Formic Acid (v/v)

**Gradient:**

Time (minutes)	%B
0	95
2	95
7	60
8	95

**Temperature:** 25°C

**Post Time:** 3 minutes

**Injection vol.:** 1μL

**Flow rate:** 0.4mL / minute

**Detection:** ESI – POS – Agilent 6210 MSD TOF Mass Spectrometer

**Sample Preparation:** 50mg strength Plavix® tablet was ground and diluted in 50:50 Solvent A / Solvent B mixture to 50mL. The solution was sonicated and filtered through a 0.45μm Nylon Syringe Filter (MicroSolv Tech Corp.).

**t<sub>0</sub>:** 0.9 minutes

## Figures:

*Fig. A: Non-degraded extract: The stock solution was diluted 1:10 with 50:50 Solvent A / Solvent B mixture. Only the API peak is observed.*

*Fig. B: Base degradation with heating: The stock solution was diluted 1:10 with 50:50 1N NaOH / Acetonitrile mixture and then heated at 85°C for 30 minutes. The API peak is no longer observed but degradants (Peak 2 and 3) are now present.*



**Attachment**

**No 258 Forced Degradation of Clopidogrel Analysis LC-MS pdf** 0.3 Mb

Printed from the Chrom Resource Center

**MicroSolv Technology Corporation**

9158 Industrial Blvd. NE, Leland, NC 28451

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

Email: [customers@mtc-usa.com](mailto:customers@mtc-usa.com)

Website: [www.mtc-usa.com](http://www.mtc-usa.com)

Date: 05-08-2024