

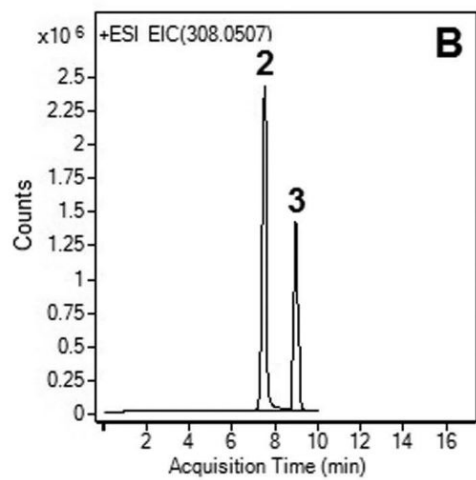
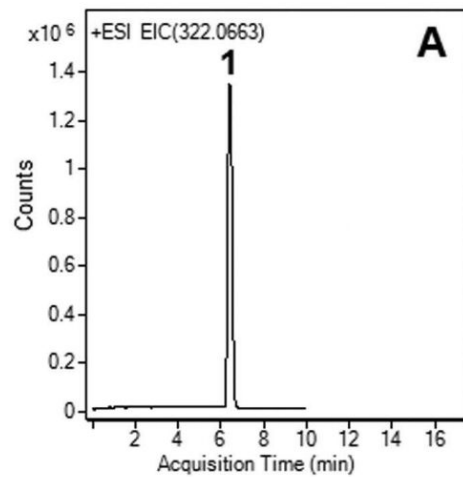


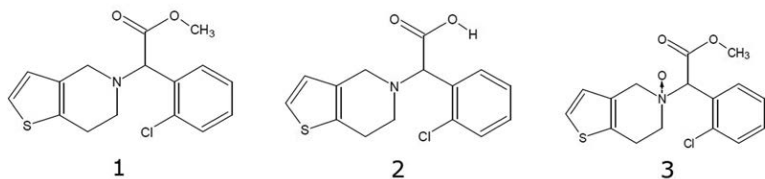
Analysis of Clopidogrel with LCMS - AppNote

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]⁺

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.).

t₀: 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.

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Attachment

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