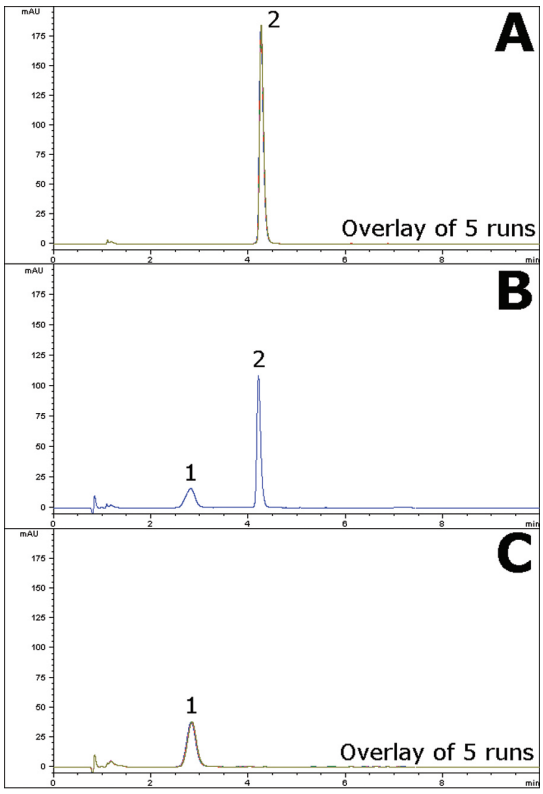
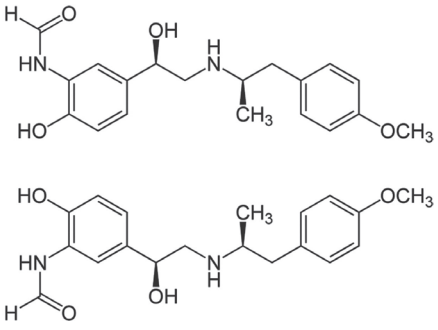
Formoterol Fumarate

Forced degradation method





Formoterol

Note: Formoterol is used a long-acting ß$_2$-antagonist used in treatment of conditions such as asthma and obstructive pulmonary disease. It is marketed under several trade names such as Foradil® and Oxeze®.

Method Conditions

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

Catalog No.: 69020-7.5P

Dimensions: 4.6 x 75 mm

Mobile Phase: A: DI H_2O / 0.1% TFA (v/v)
B: Acetonitrile / 0.1% TFA (v/v)

Gradient:

time (min.)	%B
0	10
1	10
7	40
8	10

Post Time: 2 min

Injection vol.: 10µL

Flow rate: 1.0 mL/min

Detection: UV 282 nm

Figures: **Fig. A:** (Non-degraded): 0.1 mg/mL formoterol fumarate in 50/50 solvent A / solvent B diluent.
Fig. B: (Acid degradation, no heating): 0.1 mg/mL formoterol fumarate in 50/50 1N HCl / acetonitrile diluent.
Fig. C: (Acid degradation, with heating): 0.1 mg/mL formoterol fumarate in 50/50 1N HCl / acetonitrile diluent after 30 min of heating at 85°C.

Peaks: 1. Degradant
2. Formoterol

t_0: 0.9 min

Discussion

Forced degradation studies are useful for developing stability indicating methods of pharmaceuticals. In this application note using the Cogent Phenyl Hydride column, separation is obtained between the API and an observed degradant formed under strong acid conditions. The non-degraded sample produced a sharp, symmetrical peak for the API, shown in Figure A. In Figure B, strong acid conditions without heating produced a degradant while the API peak was still present. In Figure C, acid degradation with heating completely converted the API into the degradant, as the API peak was no longer observed.

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