

Abstract

Forced Degradation Studies on Agents of Therapeutic Interest [†]

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Abstract: Chalcones possessing potential anti-Alzheimer's activity were synthesised in our lab using the Claisen Schmidt reaction. FDS (Forced degradation protocols) protocols in accordance with ICH (International Conference on Harmonization) guidelines were applied to three thiophene chalcones TC1, TC2, and TC3. The method was developed using Thermo Scientific C18 column (Agilent Technologies India Ltd., Mumbai, India 250 × 4.6 mm, 5 µm) as stationary phase and sodium acetate buffer (pH 3.0), with acetonitrile (40:60, v/v; 40:60, v/v; 25:75, v/v, respectively) as the mobile phase at 1 mL/min flow rate and 280 nm as detection wavelength. The developed method was successful in resolving TC1, TC2 and TC3 from its degradation products. TC1, TC2 and TC3 were eluted at a retention time of 10.5 min, 27.4 min and 10.2 min, respectively. HPLC (High Performance Liquid Chromatography) method was developed and validated for the individual untreated molecules and was found to be specific, selective, precise, reproducible, robust and linear in the range of about 5–15 ppm of the working standard concentration. The chalcones were stable under thermal and thermal-humidity stress, but degraded to different extents under acid-and base-catalysed hydrolysis, oxidative stress and photolytic conditions, as seen by HPLC analysis. The degradation of TC1 was studied by LC-MS and predictions of the mechanism of degradation were attempted.

Keywords: thiophene chalcone; analytical method; forced degradation studies

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