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Structural Elucidation of Novel Degradation Products of Pioglitazone by Nuclear Magnetic Resonance Spectroscopy and High Resolution Mass Spectrometry

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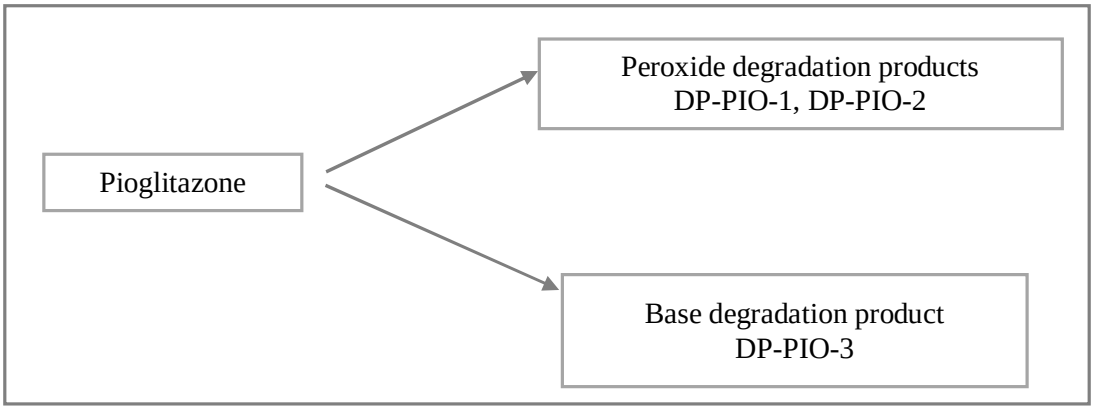
ABSTRACT

Pioglitazone hydrochloride is an anti-diabetic agent and it is used to treat type 2 diabetes. It is a class of thiazolidinediones and it was subjected to stress degradation under acidic basic and peroxide hydrolysis according to ICH guidelines-stability testing of new drug substances and products Q1A(R2). The thiazolidinediones group was cleaved and rearranged under base and peroxide mediated hydrolysis and stable in acidic hydrolysis conditions. Two major degradants referred as DP-PIO-1, DP-PIO-2 were formed during peroxide hydrolysis and one degradant which is referred as DP-PIO-3 was formed in base catalyzed hydrolysis. These impurities were isolated by using preparative HPLC, DP-PIO-1 and DP-PIO-2 are novel degradants and structures were elucidated by Nuclear Magnetic Resonance Spectroscopy (1D,2D NMR) along with High Resolution Mass Spectrometry.

Graphical Abstract



Keywords: Pioglitazone degradation products, Structure elucidation, HRMS, NMR.