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Identification of Methyl-biphenyltetrazole as a novel degradation product of irbesartan

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I rbesartan is amongst the most commonly prescribed antihypertensive drugs and has the potential to offer advantages in safety and tolerability over previous classes of drugs in the treatment of hypertension, diabetic nephropathy and heart failure. The aim of the present study was to investigate the instability of irbesartan in aqueous solution and identify the degradants formed using high performance liquid chromatographic method.

Method: The instability of irbesartan in aqueous solution was determined at 70° C. The aqueous solutions used were borate buffer (pH 9.8) and ammonia (2N). Separation of the degradants was achieved with Hitachi LC 6200 pump, LC Organizer injector, Kratos Spectroflow 783 detector and zorbax analytical column C_{18} (150 mm X 4.6 mm, 3.5 µm). The mobile phase consisted of 1% acetic acid in methanol (30:70). Elemental and Infrared spectroscopic analyses were used to characterize the degradants.

Results: One degradant was identified in irbesartan degradaed aqueous solution. Infrared spectroscopic analysis revealed that the carbonyl functional group (C=O : 1730 cm⁻¹) of the lactam ring and the α -methylene group (α -CH2 :1400 cm⁻¹), both present in irbesartan were found to be absent in the degradant. The elemental analysis showed the percentage compositions of the elements to be correct.

Conclusion: The mobile phase employed in the HPLC separation was effective for the separation of irbesartan from its degradant. The degradant in irbesartan degradaed aqueous solution was identified by elemental and infrared spectroscopic analyses and confirmed as Methyl-biphenyltetrazole.

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