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Degradation Study of Valsartan: Isolation and Structural Elucidation of Novel Degradants

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ABSTRACT

To describe the stability of Valsartan under stress conditions and to identify the degradation products. Valsartan was subjected to hydrolytic, oxidative, thermal and photolytic stress conditions as per ICH guidelines. The drug showed degradation only in peroxide condition, while it was stable to other stress conditions. Two degradation products (DP) were formed, identification of the DP's was performed by using mass spectrometry coupled to ultra-performance liquid chromatography (UPLC-MS) and were separated on a C18 column by using Autopurification mass spectrometer (APMS) system by using gradient elution. The structures were established by 1D and 2D NMR spectroscopic studies and HRMS. The products were identified as N-((2'-(2H-tetrazol-5-yl)-[1,1'-biphenyl]-4-yl)methyl)pentanamide (DP-1), N-pentanoyl-N-(tetrazolo[1,5-f]phenanthridin-6-ylmethyl)-L-valine (DP-2). Both the degradants are novel.

High Lights:

- Valsartan was subjected to force degradation under acidic, basic, oxidative, photolytic and thermal conditions as per ICH guidelines.
- In Acid and base degradation no degradants were formed.
- In Oxidative degradation two degradant products were formed.

Keywords: Valsartan, degradation products, HRMS, ^{1}H NMR, ^{13}C NMR, gCOSY, ^{1}H-^{13}C gHSQC, ^{1}H-^{13}C gHMBC, ^{1}H-^{15}N gHSQC and ^{1}H-^{15}N gHMBC.