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Separation and characterization of the hydrolytic degradation products of amlodipine and atorvastatin and development of RP-HPLC method for quantitative determination in bulk powder and dosage form

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Amlodipine (AML) and atorvastatin (ATV) were subjected to acidic hydrolysis and their degradation products were separated and their structures were confirmed. A simple stability indicating isocratic reversed phase high performance liquid chromatographic method was developed and validated for the simultaneous determination of AML and ATV in presence of their hydrolytic degradation products. The proposed RP-HPLC method utilizes Agilent Zorbax® ODS 5 um, 4.6 x 250 mm column, at ambient temperature, mobile phase consisting of acetonitrile:methanol:phosphate buffer solution (45: 30: 25 by volume), pH adjusted to 2.5±0.1 with orthophosphoric acid, at a flow rate of 1.0 mL/min and UV detection at 254 nm. The proposed method was valid in the range of 0.8–30 µg/mL (r=0.9999) for AML and 0.4-30 µg/mL (r=1.0000) for ATV. The degradation products did not interfere with the determination of both drugs and the assay can thus be considered stability-indicating. The proposed method was validated according to ICH guidelines and successfully applied to the estimation of AML and ATV in bulk powder and pharmaceutical dosage forms.

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Degradation and characterization of impurities of new drug candidate using advance analytical techniques

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One of the most important considerations in the drug discovery process is safety, not only of the drug itself, but also impurities and degradation products. Impurities present in the API have to be identified to make sure no mutagenic or toxic substances will be administered to patients. Drug product degradation profiles need to be established to guide stable formulation and provide suitable drug shelf life assessment. Drug regulatory agencies also have requirements for characterization of the impurity profile of a pharmaceutical. Structural characterization of impurities and degradation products in bulk drug substances is an integral part of pharmaceutical product development. The analysis of these low level unknown impurities and degradants can be very challenging. Various regulatory authorities like ICH, USFDA, Canadian Drug and Health Agency are emphasizing on the purity requirements and the identification of impurities in Active Pharmaceutical Ingredient's (API's). Impurity and degradant structure elucidation is a collaborative effort involving the analytical chemist, and/or formulation as well as experts in degradation, mass spectrometry, and nuclear magnetic resonance. Identification of the degradation sample set leads to understating of degradation mechanism. In present scenario, advancement in the conventional instrumental techniques are fast characterization of impurities and related substances/ degradation products spectral analysis and isolation, using new analytical techniques, like UPLC, LC-MS, GC-MS, SFC-MS, LC-NMR, CE-MS etc. The conventional technique included separation and identification of impurities or related substances (RS) by suitable method. Eventually they are isolated and followed by characterization using various spectroscopic techniques. The new advance concept is their characterization by the use advance analytical techniques.

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