DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF ATORVASTATIN CALCIUM AND VITAMIN D_3 IN BULK AND SOLID DOSAGE FORM

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Abstract

The RP-HPLC method has shown adequate separation of Atorvastatin Calcium and Vitamin D_3in bulk and its synthetic mixture. The separation was achieved on a Phenomenex C18 (250mm X 4.6 mm i.d., 5 µm particle size) with a gradient system of Acetonitrile: Methanol in the ratio of 75:25 v/v, pH adjusted 3.5 with ortho-phosphoric acid. The mobile phase at a flow rate of 1.2 ml/min, Injection volume 20µl and wavelength of detection used was 249 nm. The retention time for Atorvastatin calcium and Vitamin D_3 was obtained as 1.7 min and 12.5 min, respectively. The linearity of the proposed method was investigated in the range of 8-28 µg/ml and 2-7 µg/ml for Atorvastatin calcium and Vitamin D_3, respectively. Correlation coefficient was 0.9984 and 0.9955 for Atorvastatin calcium and Vitamin D_3, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Atorvastatin calcium and Vitamin D_3. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets.

Key words: Atorvastatin calcium, Vitamin D_3, RP-HPLC Method, Analytical Method Validation.