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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF ATORVASTATIN CALCIUM AND VITAMIN D_3 IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT: Purpose: To develop and validate a novel reverse phase high performance liquid chromatographic (RP-HPLC) method for the estimation of atorvastatin and vitamin D3 in pharmaceutical dosage form. The RP-HPLC Method has shown adequate separation of Atorvastatin Calcium and Vitamin D_3 in Bulk and its synthetic mixture.

Method: Chromatographic identification was achieved on Phenomenex C18 (250mm x 4.6mm 5µm particle size) column with mobile phase using Acetonitrile: Methanol ratio of 75:25 v/v, pH 3.5 adjusted with ortho-phosphoric acid and flow rate is 1.2 ml/min. Sample injection volume is 20 µl and detection wavelength at 252 nm. The developed HPLC method was validated according to International Conference on Harmonization (ICH) Q2 (R1) guidelines.

Result: The retention time for Atorvastatin calcium and Vitamin D_3 was obtained as 2.9 min and 16.6 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 guidelines, for its accuracy, precision, LOD & LOQ.

CONCLUSION: The method was developed successfully and the results of developed method were found satisfactory, thus the method is specific, rapid, simple and sensitive for estimation of Atorvastatin Calcium and Vitamin D_3.

KEYWORDS: Atorvastatin Calcium, Vitamin D3, RP-HPLC, Method Development, Validation

I. INTRODUCTION