

**DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR
SIMULTANEOUS ESTIMATION OF ATORVASTATIN CALCIUM AND
IRBESARTAN IN THEIR PHARMACEUTICAL DOSAGE FORM.**

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ABSTRACT

A simple, accurate, and precise UV spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Atorvastatin Calcium and Irbesartan in their Pharmaceutical Dosage Form. A simple and sensitive UV spectrophotometric method has been developed by Simultaneous equation method in which determination was carried out at 246nm λ_{max} of Atorvastatin Calcium and 228nm λ_{max} of Irbesartan. The calibration curves were linear in a concentration range of 6-26 $\mu\text{g/ml}$ for Atorvastatin Calcium and 8-18 $\mu\text{g/ml}$ for Irbesartan at their respective wavelength. In the combined Dosage Form both the drugs were estimated as 99.20% and 99.66% Atorvastatin Calcium and Irbesartan respectively. The RP-HPLC method was performed on ProntoSIL C18 column (150mm X 4.6 mm i.d., 5 μm particle size) with a gradient system of Acetonitrile : Buffer (pH 3.5) in the ratio of 55:45 v/v with a flow rate of 1.0 ml/min, injection volume 20 μl and detection wavelength was 245nm. The retention time for Atorvastatin Calcium and Irbesartan was obtained as 5.930 \pm 0.05min and 2.92 \pm 0.1min respectively. The linearity of the proposed method was investigated in the range of 2-10 $\mu\text{g/ml}$ and 15-75 $\mu\text{g/ml}$ for Atorvastatin Calcium and Irbesartan respectively. Correlation coefficient was 0.9992

and 0.9994 for Atorvastatin Calcium and Irbesartan respectively. The developed method was validated as per ICH guidelines, for its accuracy, precision, LOD & LOQ and satisfactory results were obtained, thus the method is specific, rapid, and sensitive for estimation of Atorvastatin Calcium and Irbesartan.

Key words: Atorvastatin Calcium, Irbesartan,
Simultaneous Equation Method, RP-HPLC, Validation.