

**Background and Objectives:**

High performance liquid chromatography (HPLC) is a separation technique that involves the injection of a small volume of liquid sample into a tube packed with tiny particles. This study examined two drug substances specifically Ibuprofen and baclofen for simultaneously quantification and determination using a simple HPLC method. The main aim of this study was to develop and validate analytical method for separation and simultaneous determination of Ibuprofen and Baclofen using HPLC coupled with UV detection.

**Method:**

An HPLC with UV detection was used to separate Ibuprofen and Baclofen. A simple, specific, precise, and accurate HPLC method was developed and validated for simultaneous determination of Ibuprofen and baclofen. The separation was achieved using reversed -phase separation column C18 (25 cm × 0.46 cm, 5 μm) with a mobile phase consisted of MeOH: Buffer (pH 3±0.05): ACN (5/30/65) V/V. The optimized method was then validated in accordance to ICH guidelines in the terms of Specificity, Accuracy, Precision, Linear range, Limit of detection, Lower limit of quantification and Robustness.

**Results:**

Different mobile phase compositions were tried and tested to develop and optimize the best chromatographic conditions for simultaneous separation of Ibuprofen and baclofen. The validation protocols showed a specific precise and accurate method. The values of accuracy for Ibuprofen and baclofen at different concentrations are calculated and founded the average recovery observed was 100.5% [99.1-102.0] for both. On the Other hand, the values of RSD for the two compounds at different concentrations are less than 1% which is the accepted value. Also, the method showed linearity were the concentration (444-16000 ppm) for Ibuprofen and (56-2000 ppm) Baclofen. LLOQ was found to be 70 and 60 ppm for Ibuprofen and baclofen respectively. LOD was set to be 20 ppm for both.

**Conclusions:**

The developed method was validated, and it was found to be simple, rapid, precise & accurate and it can be used for routine analysis of Ibuprofen and Baclofen in pharmaceutical dosage forms. The forced degradation studies were carried out in accordance with ICH guideline and the results revealed suitability of the method to study stability of Ibuprofen and Baclofen under various degradation conditions like acid, alkali, oxidative, thermal, photolysis. Finally, it was concluded that the method is simple, rapid, precise & accurate.

**Key Words:** HPLC, Ibuprofen Baclofen, Validation ICH