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## Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of NSAIDS-Antiulcer Agent Combination

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**Abstract :** A specific, accurate, precise and reproducible stability-indicating HPLC method has been developed and subsequently validated for the simultaneous determination of Paracetamol (PCM), Pantoprazole (PPZ) and Ibuprofen (IBU) in pharmaceutical dosage forms. The separation was performed on a Rankem Princeton Spher-100,  $C_{18}$  (150×4.6mm), 100A, 5µm column using methanol: disodium hydrogen phosphate buffer (adjusted to pH 7 using orthophosphoric acid) in the ratio of 60:40 (v/v) as the mobile phase. The flow rate was adjusted to 1ml/min for PCM, PPZ and 1.5ml/min for IBU. Quantitation was achieved with UV detection at 222 nm, based on peak area with linear calibration curves, at seven concentration levels ranging from 1-64µg/ml for PCM, PPZ and IBU in individual as well as in combined dosage form. It demonstrated good linearity with  $r^2 > 0.998$  for all the drugs. The method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantitation and robustness. The proposed method was successfully applied for the analysis of pharmaceutical formulations containing PCM, PPZ and IBU, in the presence of degradation products formed under various stress conditions, and no interference from the excipients was observed. **Keywords:** RP-HPLC, Paracetamol, Pantoprazole, Ibuprofen, Stability-indicating method.

## Introduction

Rheumatoid arthritis is a long–lasting chronic autoimmune disorder characterized by joint swelling, joint tenderness, and destruction of synovial joints, leading to severe disability and premature mortality. This may result in a low red blood cell count, inflammation around the lungs and the heart. Fever and low energy may also occur. The cause of rheumatoid arthritis is not very clear but it is believed to involve a combination of genetic and environmental factors. Family history is an important risk factor because it is strongly associated with the inherited tissue type major histocompatibility complex (MHC) antigen HLA-DRB1 and the gene PTPN22 and PAD14. The clinical manifestation of Rheumatoid Arthritis (RA) can be preceding by the presence of autoantibodies, such as rheumatoid factor (RF) and anti-citrullinated protein antibody (ACPA)<sup>1, 2, 3</sup>. The inflammation and thickening of the joint capsule is due to the body's immune system attacking the joints. It also affects the underlying bone and cartilage. RA primarily affects joints, but it also affects other organs in more than 15-25% of individuals. People with RA are more prone to atherosclerosis, risk of myocardial infraction, stroke, fibrosis of the lungs and renal amyloidosis can occur as a consequence of chronic inflammation <sup>4</sup>. The goal of the treatment is to reduce pain, decrease inflammation, and improve a person's overall functioning and this may be helped by exercise, balancing rest and the use of splints and braces, pain medications, steroids, and NSAIDs<sup>5</sup>.