

Application of Liquid Chromatographic Method for the in vitro Determination of Gastric and Intestinal Stability of Pure Andrographolide in the Extract of *Andrographis paniculata*

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Abstract : Gastrointestinal stability of andrographolide was evaluated in vitro in simulated gastric (SGF) and intestinal (SIF) fluids using a validated HPLC-PDA method. The method was validated using a 5µm ThermoHypersil GOLD C18column (250 mm × 4.0 mm) and mobile phase consisting of water: acetonitrile; 70: 30 (v/v) delivered isocratically at a flow rate of 1 mL/min with UV detection at 228 nm. Andrographolide in pure form and extract *Andrographis paniculata* was incubated at 37°C in an incubator shaker in USP simulated gastric and intestinal fluids with and without enzymes. Systematic protocol as per FDA Guidance System was followed for stability study and samples were assayed at 0, 15, 30 and 60 min intervals for gastric and at 0, 15, 30, 60 min, 1, 2 and 3 h for intestinal stability study. Also, the stability study was performed up to 24 h to see the degradation pattern in SGF and SIF (with enzyme and without enzyme). The developed method was found to be accurate, precise and robust. Andrographolide was found to be stable in SGF (pH ~ 1.2) for 1h and SIF (pH 6.8) up to 3 h. The relative difference (RD) of amount of drug added and found at all time points was found to be < 3%. The present study suggests that drug loss in the gastrointestinal tract takes place may be by membrane permeation rather than a degradation process.

Keywords : andrographolide, *Andrographis paniculata*, in vitro, stability, gastric, Intestinal HPLC-PDA

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