This open-label, single-dose, parallel-group study (September 2008–April 2009) investigated bilastine pharmacokinetics in renal insufficiency. Four groups (n=6 each) received a single 20mg oral dose: healthy subjects (GFR >80 mL/min/1.73 m²) and those with mild (50–80), moderate (30–50), and severe (≤30) renal insufficiency (GFR assessed by iothalamate clearance). Strict inclusion/exclusion criteria were applied, ensuring participants were either infertile or using double-barrier contraception. Blood and urine samples were collected at various time points post-dose, with bilastine quantified using .LC/MS/MS. The study adhered to Declaration of Helsinki, FDA, EMA, ICH, and GCP guidelines