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(57) Abstract :
The present invention relates to the formulation and evaluation of an immediate-release oral tablet of Ciprofloxacin Hydrochloride designed to achieve rapid disintegration, enhanced dissolution, and improved patient acceptability. The formulation employs a drug–resin complex (DRC) approach using Kyron T-314 to effectively mask the drug's bitterness and enhance solubility. The tablets were prepared by the direct compression method, utilizing Mannitol as a diluent, Hydroxypropyl methylcellulose (HPMC) as a binder, Kyron T-314 as a superdisintegrant and taste-masking agent, Microcrystalline cellulose (Avicel PH-101) as a filler, Saccharine as a sweetener, Talc as a glidant, Magnesium stearate as a lubricant, and Vanilla flavoring to improve palatability. Nine formulations (F1–F9) were developed by varying concentrations of HPMC and Kyron T-314 to optimize tablet performance. The optimized formulation (F9) exhibited superior physical and dissolution characteristics with a disintegration time of 47 ± 1.8 seconds, hardness of 5.2 ± 0.2 kg/cm², drug content of 99.5 ± 0.4%, and cumulative drug release (CDR) of 98.6 ± 0.8% within 3 minutes. Drug release kinetics followed a Zero-order model ($R^2 = 0.9783$) and exhibited non-Fickian (anomalous) diffusion, indicating both diffusion and polymer relaxation mechanisms. Stability studies conducted under accelerated conditions (40 ± 2°C / 75 ± 5% RH) for three months demonstrated no significant changes in hardness, disintegration, or drug content, confirming excellent physical and chemical stability. The invention provides a cost-effective, scalable, and pharmaceutically stable immediate-release formulation that ensures rapid therapeutic onset, improved taste masking, and enhanced bioavailability of Ciprofloxacin Hydrochloride compared to conventional dosage forms.

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